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No. 97-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

TEMPIE FORTSON WORTHY,

Petitioner,

v.

COLLAGEN CORPORATION,

Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of Texas

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In light of this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), holding that none of the plaintiffs' state-law personal-injury claims were preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. 360c *et seq.*, did the Texas Supreme Court err in holding that petitioner's claims are preempted here simply because the Food and Drug Administration granted pre-market approval for the medical device alleged to have caused petitioner's injuries?

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Tempie Fortson Worthy seeks a writ of certiorari to challenge the Texas Supreme Court's ruling that all of her state-law damages claims under the Texas Deceptive Trade Practices--Consumer Protection Act ("DTPA") alleging injuries caused by a medical device are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act.

This Court should grant review for two related reasons. **First**, the Court should resolve a split of authority in the federal and state appellate courts over the meaning of this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), which held that none of the damages claims at issue there were preempted by the MDA. Indeed, respondent Collagen Corporation itself has twice sought review on the same issue as presented here, at a time when the post-*Medtronic* chaos was less pronounced than it is today. *See Collagen Corp. v. Fiore*, 118 S. Ct. 684 (1998) (No. 96-1611); *Collagen Corp. v. Green*, 117 S. Ct. 1695 (1997) (No. 96-1451).

We acknowledge that the Court has recently denied review in a case presenting the same issue in the same procedural posture. *See Mitchell v. Collagen Corp.*, 118 S. Ct. 1300 (1998) (No. 97-1018). However, as the Texas Supreme Court recognized (27a-32a), the lower courts are in sharp disagreement on the question presented—whether claims relating to medical devices that have undergone the MDA's pre-market approval ("PMA") process are preempted. Thus, some courts have held that the damages claims here come within *Medtronic*'s no-preemption holding, but others have held that they do not because the device in *Medtronic* had not undergone PMA, but had been cleared for marketing under a different provision of the MDA.

Second, the Court should grant review because a significant number of appellate courts have erroneously reaffirmed broad pre-*Medtronic* interpretations of the MDA's preemption

provision, 21 U.S.C. 360k(a). Like the Texas Supreme Court below, those courts have failed to follow *Medtronic*'s holding that claims based on state-law duties of general applicability are not preempted under section 360k(a) and have mistakenly concluded that PMA is a preemptive "requirement" under that section and thereby eliminates all state-law claims for money damages. *See Medtronic*, 116 S. Ct. at 2258.

OPINIONS BELOW

The opinion of the Texas Supreme Court is not yet officially reported, but appears at 1998 Tex. Lexis 22, and is reproduced in the appendix at 1a. The orders of the 192nd Judicial District Court, Dallas County, are unreported and are reproduced in the appendix at 40a and 42a. The opinion of the Texas Court of Appeals is reported at 921 S.W.2d 711 (Tex. App. 1995), and is reproduced in the appendix at 44a. The opinion of the Texas Court of Appeals on rehearing is reported at 921 S.W.2d 721 (Tex. App. 1995), and is reproduced in the appendix at 67a. The order of the Texas Court of Appeals on a subsequent request for rehearing is unreported, and is reproduced in the appendix at 74a.

JURISDICTION

The judgment of the Texas Supreme Court, which finally disposed of all of petitioner's claims, was entered on February 13, 1998. This Court has jurisdiction under 28 U.S.C. 1257.

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. 360k(a) provides in part:

Except as provided in subsection (b) of this section, no

State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose

> of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. ...

STATEMENT OF THE CASE

In February 1991, petitioner Tempie Fortson Worthy received injections of a medical device called Zyderm, a brand of injectable bovine collagen marketed by respondent Collagen Corporation as a method to smooth out rough or damaged skin. Ms. Worthy alleges that Zyderm caused her severe autoimmune disease. Second Amended Petition, at 5. This petition presents the question whether Ms. Worthy may seek recovery for her injuries under Texas law, or whether, as respondent maintains, the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act, that were enacted in 1976 to protect consumers from potentially dangerous medical devices, bar Ms. Worthy from recovering any damages for injuries under state law.

Part A below describes the structure of the MDA, and Part B briefly explains the initial proceedings in this case. Part C discusses this Court's decision in *Medtronic v. Lohr*, which interpreted the MDA's preemption provision and has spawned a wide divergence in the state and federal appellate courts on the meaning of that provision. Finally, Part D describes the holding of the Texas Supreme Court currently under review.

A. The Medical Device Amendments.

The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous medical devices and providing a structure through which devices would reach the market. H.R. Rep. 853, 94th Cong., 2d Sess.

1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. 360c *et seq.*). Three components of this regulatory structure are relevant to this petition.

First, every medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853, *supra* at 34; 21 U.S.C. 360c(a). Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the Food and Drug Administration ("FDA"), the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). Thus, the FDA may subject them to "special controls," such as the agency's specific warning label for tampons. *See* 21 C.F.R. 801.430(c),(d)&(e).

Finally, class III devices—such as collagen or the pacemaker at issue in *Medtronic*—are those that cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). This process is known as pre-market approval ("PMA"). *Id.* § 360e(b)(1)(A). However, if the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device 21 U.S.C. 360e(b)(1)(B), 360c(f)(1)(A).

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, in addition to the tampon warning label mentioned above, the FDA has required that hearing aids bear certain

labels. *See* 21 C.F.R. 801.420. The FDA has never promulgated any such device-specific requirements for collagen.

Third, the MDA contains a preemption provision, 21 U.S.C. 360k(a), which preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to" conflicting MDA "requirements." Under 21 U.S.C. 360k(b), the FDA has the authority to exempt from preemption certain state requirements that would otherwise be preempted. Thus, the FDA has issued regulations concerning the scope of MDA preemption, *see generally* 21 C.F.R. Part 808, which reflect section 360k(a)'s narrow reach. *See Medtronic*, 116 S. Ct. at 2257 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation"). For instance, the regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. 808.1(d). Likewise, to be preempted, state-law requirements also must be "specific." Thus, according to the FDA, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates ... to other products in addition to devices." *Id.* § 808.1(d)(1). Such requirements of general applicability specifically include state unfair trade practices laws, such as the DTPA under which petitioner seeks recovery. *Id.*

B. Facts and Pre-*Medtronic* Proceedings Below.

In February 1991, petitioner Tempie Fortson Worthy received injections of Zyderm. Second Amended Petition, at 2. Zyderm is a class III medical device for which respondent obtained FDA pre-market approval in 1981 (6a). Shortly after the injections, Ms. Worthy became ill and developed a debilitating autoimmune disorder, causing her permanent scarring and disfigurement and requiring reconstructive plastic surgery. Second Amended Petition, at 5; Orig. Petition, at 6.

Ms. Worthy filed suit in the 192nd Judicial District Court of Dallas County, Texas, seeking damages from respondent under Texas common law on the ground that respondent did not properly inspect, design, or manufacture Zyderm, nor warn about its propensity to cause autoimmune injuries. First Amended Petition, at 2-3. She later filed a second amended petition alleging the violations of the Texas Deceptive Trade Practices Act at issue in this petition. *See* Tex. Bus. & Com. Code 17.41 *et seq.*[1]

As part of her DTPA complaint, petitioner alleged that respondent's representations that Zyderm was safe for patient use were false and deceptive and caused her serious immunological injuries, including physical deformities. Second Amended Petition, at 2-3. She further alleged that respondent violated DTPA section 17.46(b) by making false representations about the quality of Zyderm. *Id.* at 3. Petitioner also alleged that respondent violated the DTPA by failing to disclose information in order to induce petitioner and other consumers to use Zyderm, which they would not have done had the proper disclosures been made. *Id.* Finally, she claimed that respondent breached the warranty of merchantability, actionable under the DTPA, because Zyderm was not reasonably fit for its ordinary purpose: injection under the skin. *Id.* at 3-4; *see* Tex. Bus. & Com. Code 17.50(a)(2). Ms. Worthy sought all actual damages, treble damages as provided by the DTPA, punitive damages, and

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[1] The Texas Supreme Court held that petitioner's non-DTPA claims were not preserved as a matter of Texas law (12a) and therefore they are not pursued in this petition. As the Texas Supreme Court held, the DTPA claims are based on the same theories of liability as Texas common-law claims for negligence, breach warranty, and on strict liability, and thus raise the same federal preemption issues (37a).

attorney's fees. Second Amended Petition, at 4-5.

Thereafter, respondent moved for summary judgment (later filing a supplemental motion to include the DTPA claims), arguing that all of Worthy's claims are preempted by the MDA. In two one-page orders, the district court granted the motions in their entirety (40a, 42a). On October 31, 1995, the Court of Appeals for the Fifth District of Texas affirmed (44a). On the basis of broad pre-*Medtronic* decisions, that court held that Zyderm's pre-market approval preempted any state-law damages claim concerning Zyderm.

Petitioner then appealed to the Texas Supreme Court, which granted discretionary review and heard argument after this Court's decision in *Medtronic*. Because of the importance of *Medtronic* to the issues before this Court, we now review that decision in detail.

C. The Decision in *Medtronic v. Lohr.*

In *Medtronic*, plaintiff Lora Lohr brought suit under Florida law for damages resulting from an allegedly defective class III pacemaker component that the FDA had cleared for marketing under its "substantial equivalence" process. This Court held that none of Lohr's claims—based on defective design, defective manufacture, and failure to warn—were preempted by the MDA.

1. *The Majority Opinion.* Although there was a partial dissent in *Medtronic*, the majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all common-law claims against device manufacturers, *Medtronic*, 116 S.Ct. at 2251 (majority); *id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part); (2) Lohr's design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 2254-55 (majority); *id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part); and (3)

A tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations are not preempted. *Id.* at 2255-56 (majority); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, the Court also held that Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 2257. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 2258.

Similarly, the Court noted that Lohr's common-law claims were not preempted because they were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court held, the general duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because of their generality, the majority ruled, the claims were outside of the prohibited category of requirements "with respect to" specific devices, within the

meaning of section 360k(a). *Id.*[2]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages suits. He therefore did not join the plurality opinion (*see supra* note 2) because he was not convinced that MDA preemption of common-law claims would be "rare." *Id.* at 2262. He joined fully, however, in the analysis set forth above and in Part V of the majority opinion, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements related to Lohr's claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulations, 21 C.F.R. 808.1(d), which amplify the meaning of section 360k(a)'s specificity requirement. 116 S. Ct. at 2260 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984)). He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.*

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. In her view, common-law claims can constitute "requirements" under section 360k(a). *Id.* at 2262-

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[2] Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages actions. *Id.* at 2252 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's analysis, none of Lohr's claims was preempted. *Id.* at 2258-59.

63. Although concurring with the majority that the Lohr's design-defect claim was not preempted, she would have held the manufacturing-defect and failure-to-warn claims preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 2264. She agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.*

D. The Decision Below.

The Texas Supreme Court affirmed the dismissal of all of petitioner's claims. The court first reviewed the PMA process and the grant of Zyderm's PMA. The court then turned to this Court's opinions in *Medtronic*, which, the court declared, "do not dispel all confusion" on the scope of MDA preemption (13a). The Texas court discerned four principles from *Medtronic*: (1) the MDA preempts only state requirements that directly conflict with federal requirements or thwart the MDA's purposes (16a); (2) the more specific a federal requirement the more likely it will have preemptive effect (19a); (3) state-law damages actions may impose "requirements" within the meaning of the MDA (21a); and (4) FDA's preemption regulations guide construction of the MDA, but are not controlling (25a).

The court then went on to discuss the division among the lower courts on the question whether a device's marketing approval constitutes a preemptive MDA requirement under section 360k(a) (27a-32a). After reviewing the FDA's view that the grant of PMA does **not** preempt state-law damages claims (32a), such as petitioner's claims here, the court held all of petitioner's DTPA claims preempted. Without citation of authority, the court asserted that the FDA's marketing approval for Zyderm constituted a finding that Zyderm was safe (38a), and held that petitioner's claims conflicted with that

"requirement."

The Texas court held, alternatively, that, even if Ms. Worthy's suit did not pose a direct conflict with the MDA, her claim was preempted because it stood as an obstacle to the accomplishment of congressional objectives (38a). The court made clear that Ms. Worthy's DTPA claims were akin to common-law negligence, warranty, and strict liability claims (37a) and that **all** damages suits "challenging the safety of Zyderm are preempted" (39a). In reaching its decision, the court did not attempt to apply *Medtronic*'s majority holding that state-law duties of general applicability, such as those typically relied on in state-law damages actions, are not preempted by section 360k(a). *Medtronic*, 116 S. Ct. at 2258.

REASONS FOR GRANTING THE WRIT

A. A Deep Post-*Medtronic* Split Exists Within The Federal And State Appellate Courts.

The decision below is illustrative of the deep post-*Medtronic* split in authority in two important and related respects. **First**, the decision below widens the division among the courts on whether *Medtronic* requires specificity on the state-law side of section 360k(a)'s preemption equation. *Medtronic* held that, under section 360k(a), common-law claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. The Texas Supreme Court "dealt" with this holding by disregarding it. Other post-*Medtronic* courts that have found preemption of damages claims have been more forthright, acknowledging *Medtronic*'s majority holding and noting that it would, if applied to the case at hand, require a ruling in favor of the plaintiff. *See, e.g., Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). Those courts have not followed this portion of the majority opinion on

the ground that it is incompatible with Justice Breyer's concurrence. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998); *Papike*, 107 F.3d at 742; *see also Steele v. Collagen Corp.*, 63 Cal. Rptr. 879, 887 (Ct. App. 1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 517 (R.I. 1997); 26a (asserting "tension" between majority opinion and Justice Breyer's concurrence).

As we discuss below (at 18-20), these appellate courts and the Texas Supreme Court erred in applying (or, as here, disregarding) the *Medtronic* majority's holding. For present purposes, however, the significance of these rulings is that they are at odds with the decisions of other appellate courts that have held that this Court meant what it said in *Medtronic*: State laws of general applicability are not among those laws targeted for preemption by section 360k(a). For instance, in *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement. The Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), but held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

Id. at 789 (quoting *Medtronic*, 116 S. Ct. at 2258) (internal citations omitted). Other appellate courts have come to the same conclusion. *See Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under §360k"); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 686 (Mich. App. 1996); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997) (same); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997) (same); *Baird v. American Medical Optics*, 693 A. 2d 904, 909-10 (N.J. Super., App. Div. 1997), *certification granted*, 700 A.2d 879 (N.J. 1997); *Kernats v. Smith Indus. Medical Sys.*, 669 N.E.2d 1300, 1309 (Ill. App.) ("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 118 S. Ct. 684 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996) (same), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *see also Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *17-*18 (N.D. Okla. Mar. 31, 1997) (same).[3]

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[3] This split in authority is particularly acute in Illinois, where, if the complaint is filed in, or removed to, federal court, the plaintiffs' claims are preempted under the decision below, but if the complaint remains in state court, there is no preemption. *See Kernats*, 669 N.E.2d 1300. A similar problem arises in California, where the state's own appellate courts are split on this question. *Compare Armstrong*, 57 Cal. Rptr. 2d 763 (no preemption), *with Steele*, 63 Cal. Rptr. 2d 879

(continued...)

Second, *Medtronic* held that, in order to have preemptive effect under 21 U.S.C. 360k(a), the federal "requirement" must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. 801.430), in contrast to the comprehensive, but general, good manufacturing and labeling regulations held not to have preemptive effect in *Medtronic*. 116 S. Ct. at 2256-57. In his concurrence, Justice Breyer suggested that an example of this type of specific federal requirement would be an FDA rule that a particular hearing-aid component be built with two-inch wires. *See* 116 S. Ct. at 2259.

Although the FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner, the Texas Supreme Court nonetheless held that the PMA process was a "specific" requirement as applied to the FDA's review of Zyderm's PMA application (36a). Other appellate courts have come to the same conclusion in cases involving collagen and other PMA devices. *E.g.*, *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997); *Steele*, 63 Cal. Rptr. at 887-88. But as the Texas Supreme Court noted (29a-30a), other appellate and trial courts have come to the opposite conclusion, holding that the PMA process is **not** a specific requirement under *Medtronic*. *See Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*,

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(preemption). *Compare also Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997) (Sixth Circuit: complete preemption), *cert. denied*, 118 S. Ct. 850 (1998) , *with Niehoff*, 950 S.W.2d 816 (Kentucky Supreme Court: no preemption).

522 N.W. 2d 679, 684 (Mich. App. 1996); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen*, 1997 U.S. Dist. Lexis 6974, *14-*15.[4]

Similarly, two appellate courts have held that tort claims concerning class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. 360j(g))—which is often a precursor to the PMA process—are not preempted because that process does not establish specific requirements under *Medtronic*. *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 117 S. Ct. 2429 (1997); *Niehoff*, 950 S.W.2d at 822. *But see Martin*, 105 F.3d 1090. *See also* 31a-32a, 6a (noting this division in appellate authority and claiming that PMA and investigational processes are comparable).

This Court should grant this petition to resolve these conflicts among the federal and state appellate courts.

B. The Decision Below Is At Odds With *Medtronic*.

Review should also be granted because, as a result of the Texas Supreme Court's serious misinterpretation of *Medtronic*, consumers injured by PMA devices are left without any damages remedy. The court below erred in two fundamental ways.

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[4] The Texas Supreme Court's explanation of these cases is potentially misleading. Among the cases that the court cites for the proposition that PMA is sufficiently specific to preempt a state-law damages action are four appellate decisions holding **no** preemption because the state-law duties under which the plaintiff sought recovery were duties of general applicability and thus not within section 360k(a)'s preemptive reach. *See* 28a-29a (citing *Mears*, *Wutzke*, *Kernats*, and *Armstrong*, all of which find no preemption under section 360k(a)).

First, the mere issuance of PMA is not a specific preemption-triggering requirement under section 360k(a). Although the criteria for issuance of a PMA are more rigorous than the marketing process at issue in *Medtronic*, 116 S. Ct. at 2247 (explaining differences), they are no more "specific." Both processes apply to class III devices generally (*id.*), and neither specifies how a product is to be designed, manufactured, or labeled. Thus, the PMA process contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. 801.420), or to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's concurrence. *Id.* at 2260. Indeed, as the Solicitor General recently pointed out, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, **not** with the FDA. Brief for the United States ("U.S. Br.") in *Smith Indus. Medical Sys., Inc. v. Kernats*, No. 96-1405 (U.S. filed Dec. 10, 1997), at 16; *cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995). Moreover, as the *Medtronic* majority noted, a manufacturer does not need FDA approval to make changes to a PMA device that will enhance product safety. *See* 116 S. Ct. at 2256 n.16 (*citing* 21 C.F.R. 814.39(d)(1)-(2)). Thus, even if a state-law damages remedy were construed as "requiring" a manufacturer to improve product safety, that remedy would not, in the language of section 360k(a), be "different from, or in addition to" a federal requirement.[5]

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[5] The FDA has proposed regulations that reiterate "the agency's longstanding view that available legal remedies, including State common law tort claims, generally are not preempted" by the MDA. 62 Fed. Reg. 65384, 65384 (Dec. 12, 1997)(to be codified at 21 C.F.R. 808.1(d)(11)&(12)). The

(continued...)

Second, the Texas Supreme Court's ruling simply disregards *Medtronic* in holding that petitioner's claims—and, in effect, **all** damages claims of any kind involving a PMA device (39a)—are preempted, even though they are premised on state-law duties of general applicability. Although the court below purported to apply the opinions in *Medtronic* carefully, the holding of the *Medtronic* majority—that state laws of general applicability are not within section 360k(a)'s preemptive reach—is discussed only briefly in an initial description of the case (22a-23a). More fundamentally, that holding cannot be found anywhere in the Texas Supreme Court's analysis as to whether petitioner's claims are preempted (27a-39a). In short, the court below simply did not do business with this Court's reasoning.[6]

In this regard, the Texas Supreme Court's failure to mention, let alone apply, 21 U.S.C. 808.1(d)(1), the FDA's longstanding

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proposed regulations provide that the grant of PMA does not, in itself, preempt state common-law actions. *Id.* at 65388 (proposed 21 C.F.R. 808.1(d)(12)). The agency's views underscore the need for this Court to review the lower courts' contrary interpretations of section 360k(a).

[6] The Texas Supreme Court's failure to analyze the state-law side of section 360k(a)'s preemption equation also cannot be squared with Justice Breyer's concurrence. Justice Breyer said that a **specific** federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a **specific** state-law requirement for a one-inch wire. *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring). Ms. Worthy's claims based on general duties under the DTPA do not present a specific state-law requirement of this kind, nor the direct sort of conflict that concerned Justice Breyer.

preemption regulation, was particularly egregious because of the regulation's direct applicability to petitioner's DTPA claims. The agency's regulations, which were accorded deference in *Medtronic*, 116 S. Ct. at 2256; *see id.* at 2260-61 (Breyer, J., concurring), provide that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to **unfair trade practices** in which the requirements are not limited to devices." 21 C.F.R. 808.1(d)(1) (emphasis added). It is undisputed that the DTPA is an "unfair trade practices" statute "of general applicability" which is "not limited to devices." Moreover, petitioner's breach of warranty claim under the DTPA is specifically preserved by the FDA's regulation, which notes that warranty laws apply generally to all consumer products and therefore are not within the scope of section 360k(a). *See id.*

Finally, the Texas Supreme Court's sweeping preemption holding overlooked the fact that petitioner's DTPA claims alleged misrepresentation, deception, and a knowing failure to disclose important facts about Zyderm, *i.e.* that respondent fraudulently induced petitioner (and other consumers) to use Zyderm and that she suffered injury as a result. Second Amended Petition, at 3. Thus, even if Zyderm's PMA established a preemptive MDA requirement and the DTPA could be said to establish requirements that might be subject to preemption—propositions with which we disagree—petitioner's misrepresentation claim cannot be preempted. The MDA does not establish requirements concerning misrepresentation or fraud nor did the FDA impose such a requirement on Zyderm. Thus, petitioner's claim that respondent deceived consumers obviously would not conflict with Zyderm's approval. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (even where federal

law preempted claims for failing to warn over and above federally-approved warning label, fraud and misrepresentation claims not preempted because they were based on more general common-law duty not to deceive).

Moreover, even if it could be said that MDA requirements demanding truthfulness in dealings with the FDA (*e.g.*, 21 U.S.C. 352(a)) were the federal-law counterparts to petitioner's state-law claim based on respondent's deception, there would still be no conflict between federal and state law. To the contrary, in *Medtronic*, the Court acknowledged that the FDA brings actions to curb violations of its good manufacturing practices rules (116 S. Ct. at 2256), but held that state-law damages actions premised on those (or any other MDA) violations are not preempted. "[T]he presence of a damages remedy does not amount to the additional or different 'requirement' that is required [for preemption] under the statute; it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Medtronic*, 116 S. Ct. at 2255 (majority); *accord id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). Thus, as with all of petitioner's DTPA claims, allowing a state-law misrepresentation claim to go forward fosters, rather than undermines, the federal interest in device regulation.

* * *

As noted at the outset, this Court has previously denied certiorari in circumstances similar to those presented by this petition. However, the divergence in lower court authority continues unabated. In December 1997, in response to this Court's request for advice in *Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, the Solicitor General explained that "the current division among the lower courts on [the preemption] issue would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." U.S. Br. at 18. And he agreed with the position of

the plaintiffs in *Smith Industries*, which is the same as that of the petitioner here: that PMA does **not** preempt state-law damages actions. *Id.* at 14-18 (Solicitor General explaining in detail why no-preemption decision in *Smith Industries* is correct). However, the Solicitor General also suggested that certiorari be denied to give the lower courts an opportunity to consider the FDA's reiteration of its longstanding view that a grant of PMA does not preempt state-law damages actions. But the Texas Supreme Court below rejected those views, while pointing out the split in lower court authority and the post-*Medtronic* "confusion" (13a), dashing the Solicitor General's hope that the current disarray might abate.[7]

In sum, review should be granted because the Texas Supreme Court's sweeping preemption holding is irreconcilable with this Court's decision in *Medtronic*. If, as the Texas Supreme Court held, Congress intended in 1976 to eliminate all damages recovery for people injured by FDA-approved medical devices, this Court should say so. If, as petitioner believes, the MDA does not bar plaintiffs' access to traditional state-law damages remedies, further delay will result in further injustice. In short, it is time for this Court to end the confusion.

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[7] The Solicitor General advised that review should be denied in *Smith Industries* principally because the ruling there was not a final judgment of the Illinois Supreme Court, as required by 28 U.S.C. 1257. *See* U.S. Br. at 10-14. That problem does not exist here.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

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May 13, 1998

IN THE SUPREME COURT OF TEXAS

No. 96-0675

TEMPIE FORTSON WORTHY,
PETITIONER

v.

COLLAGEN CORPORATION,
RESPONDENT

On Application for Writ of Error to the Court of Appeals
for the Fifth District of Texas

Argued on December 17, 1996

JUSTICE HECHT delivered the opinion of the Court.

The principal issue before us is whether the Medical Device Amendments of 1976 to the federal Food, Drug and Cosmetic Act preempt this action against a manufacturer brought under the Texas Deceptive Trade Practices--Consumer Protection Act for damages resulting from the injection of a collagen implant material that is a class III medical device under the Act and that has received premarketing approval from the federal Food and Drug Administration. To resolve the issue we must construe and apply the United States Supreme Court's recent opinions in *Medtronic, Inc. v. Lohr*, __U.S.__, 116 S. Ct. 2240 (1996). We agree with the lower courts, 921 S.W.2d 711, that this action is preempted.

I

Tempie Fortson Worthy sued Collagen Corporation and Dr. James Gilmore, alleging that she was injured when Dr. Gilmore injected her with Zyderm (R) and Zyplast (R) ("Zyderm"), products manufactured by Collagen for cosmetic use. Zyderm is made from a purified form of bovine dermal collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. The collagen is processed so that it will be accepted by the human body, and the product is injected into connective tissue to repair soft tissue deformities such as scars, pockmarks, and wrinkles, caused by disease, trauma, surgery, or aging. Worthy alleges that these injections caused her to suffer autoimmune disease and physical deformities.

The federal Food and Drug Administration has determined that Zyderm is a Class III medical device as defined by the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act ("the MDA", "the FDCA", or "the Act") -- that is, a device that either is for "use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or []presents a potential unreasonable risk of illness or injury". 21 U.S.C. § 360c(a)(1)(C)(ii). With certain exceptions, a Class III device may not be marketed without FDA approval. *Id.* §§ 331(a), 351(f); *Medtronic*, __U.S. at__, 116 S. Ct. at 2246-2247. To obtain approval, a person must provide the FDA with "reasonable assurance" that the device is both safe and effective. 21 U.S.C. § 360e(d)(2); *Medtronic*, __U.S. at__, 116 S. Ct. at 2246. "The safety and effectiveness of a device are to be determined -- (A) with respect to the persons for whose use the device is represented or intended, (B) with

respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2). "The process of establishing this 'reasonable assurance,' which is known as the 'premarket approval,' or 'PMA' process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic*, ___U.S. at___ , 116 S. Ct. at 2246-2247; see 21 U.S.C. § 360e(c); 21 C.F.R. 814.1-.126 (1997).

Specifically, a PMA application must contain:

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) . . . adequate information to show that [any aspect of the device subject to certain performance standards] fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as [the FDA] may reasonably require . . .;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as [the FDA] may require.

21 U.S.C. § 360e(c)(1). The PMA application must also include: "[a] general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended", 21 C.F.R. § 814.20(b)(3)(i); "an explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and perfomance characteristics of the device", *id.* § 814.20(b)(3)(ii); "[a] description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended", *id.* § 814.20(b)(3)(iii); "[a] discussion demonstrating that the data and information in the application constitute valid scientific evidence . . . and provide reasonable assurance that the device is safe and effective for its intended use", *id.* § 814.20(b)(3)(vi); and a discussion of the "benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA", *id.* These are but a few of the requirements for a PMA application. *See* 21 C.F.R. § 814.20.

A PMA application is ordinarily referred to a panel of experts for study. 21 U.S.C. §§ 360e(c)(2), 360c(b). When the study is completed, the panel gives the FDA "a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation." *Id.* § 360e(c). The FDA grants premarketing approval only if it finds reasonable assurance that the device is safe and effective with respect to the conditions of use prescribed, recommended, or suggested in the labeling, that the manufacturing and processing methods and facilities are satisfactory, and that the proposed labeling is not false or misleading in any manner. 21 U.S.C. § 360e(d)(2); *see also* 21 C.F.R. § 814.44. A device approved for marketing cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80.

A device manufacturer must promptly report to the FDA any malfunctions of a device or any deaths or serious injuries caused by it. 21 C.F.R. § 803.1 (1997). The FDA is authorized to notify the public of risks presented by medical devices, 21 U.S.C. § 360h(a); to require manufacturers to repair or replace defective devices, *id.* § 360h(b); to institute recall campaigns, *id.* § 360h(e); to require that records and reports be made of adverse reactions, serious injuries, and death associated with devices, *id.* § 360i; to require postmarketing surveillance of devices, *id.* § 360l; and to withdraw marketing approval if it finds that an approved device is not safe and effective, *id.* § 360e(e).

There are three exceptions to the PMA requirement. One is for devices marketed prior to May 28, 1976. They can

continue to be marketed pending the FDA's completion of the PMA process. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (1997). A second is for devices "substantially equivalent" to devices marketed before May 28, 1976. 21 U.S.C. § 360e(b)(1)(b). They also can be marketed pending completion of the PMA process, but they are subject to a premarket notification process, referred to as a "§ 510(k) process" (after the relevant provision of the statute before codification). 21 U.S.C. §§ 360e(b)(2), 360(k); 21 C.F.R. § 814.1(c)(1) (1997); *Medtronic*, ___U.S. at___, 116 S. Ct. at 2247. A third exception is for devices being investigated for human use. They cannot be used without FDA approval obtained through a process different from the PMA process but involving comparably rigorous review. 21 U.S.C. 360j(g); 21 C.F.R. 812.1-.150 (1997).

None of these exceptions applied to Zyderm. Collagen applied for premarketing approval of its product in May 1980. The initial application consisted of eight volumes containing safety and effectiveness data, in vitro data, animal data, clinical data from tests with more than five thousand patients, a statement of ingredients, a reference to performance standards, labeling, a bibliography, significant articles, manufacturing methods, product samples, and patient report forms. While the application was pending, Collagen amended it to correct deficiencies noted by the FDA. In July 1981 the FDA approved Zyderm subject to several conditions. The FDA restricted Zyderm to prescription use and required that it be distributed with FDA-approved labeling and with a patient manual. The FDA also required that "no advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall

state the indications, contraindications, warnings, precautions and adverse effects of the device." The FDA required that patient studies continue under specified guidelines and that patients be monitored for adverse reactions to the product. Finally, the FDA required Collagen to submit a supplemental PMA before making any changes "that may affect the safety or effectiveness" of Zyderm, including changes in use; labeling; manufacturing facilities, methods, or quality control procedures; subcontractors, suppliers, or distributors; sterilization procedures; packaging; and performance or design specifications, components, or ingredients. Changes to enhance safety could be made after notice to the FDA and before approval, such as the addition of warnings, contraindications, or side effects; deletion of misleading, false, or unsupported indications; and changes in the manufacturing process or quality controls to provide additional assurance of purity, identity, strength, or reliability. The FDA published notice of its premarketing approval order in the Federal Register. 46 Fed. Reg. 46394 (1981).

In 1989, Collagen filed a supplemental PMA application requesting the FDA's approval of certain labeling changes. The FDA granted Collagen's application but again imposed strict limitations on the labeling of the product and any further changes. Additionally, the FDA required Collagen to add warnings to its product that soft tissues may not return to their original shape and texture after collagen implantation, and that patients should not receive such implants if they desire only temporary effects. These additional requirements were precipitated by media stories concerning collagen implants.

In July 1991, Congressman John D. Dingle, Chairman of the Oversight and Investigations Subcommittee of the House

of Representatives Committee on Energy and Commerce, wrote the FDA of his concerns regarding the frequency and severity of adverse reactions to Zyderm, both local and systemic immune-related. Congressman Dingle asserted that many such reactions were not being reported to the FDA as required by the conditions of Collagen's PMA approval, and that Stanford University and Collagen had committed numerous serious violations of good clinical practices and failed to report to the FDA significant adverse immunologic events which occurred during the Zyderm clinical trials. Congressman Dingle asked the FDA to reevaluate the validity and reliability of the clinical trials supporting Collagen's PMA application. The FDA complied, completing the process in February 1992. While the FDA found shortcomings in the review of Collagen's PMA application and the decision to grant approval, it nevertheless concluded that approval was appropriate. After making numerous specific and detailed findings, the Director of the FDA's Office of Device Evaluation concluded that no issues had been raised regarding the safety and effectiveness of Zyderm to warrant withdrawing of marketing approval.

Worthy received her injections in February 1991 and filed this suit in October 1992. In her original petition Worthy alleged: that Collagen was negligent and grossly negligent in designing, manufacturing, and distributing Zyderm, in failing to warn adequately of the risks of its use, in failing to report adverse reactions to the FDA, in failing to test and monitor product use, and in mislabeling the product; that Collagen breached express and implied warranties relating to Zyderm; that Collagen was strictly liable for Zyderm because its defective design, manufacture, and marketing made it unreasonably dangerous; and that Collagen had fraudulently

misrepresented information to and concealed information from the FDA and the public. The district court granted summary judgment for Collagen on the ground that all these claims were preempted by the FDCA. Because Dr. Gilmore, Worthy's physician, remained a defendant in the case, the summary judgment for Collagen was interlocutory. Worthy then amended her pleadings to assert a DTPA cause of action against Collagen and nonsuited Gilmore. The court again granted summary judgment for Collagen on preemption grounds, and Worthy appealed. The court of appeals held that Worthy's DTPA action was preempted and that she had failed to preserve for appeal any complaint concerning her other claims because she had not included in the appellate record the pleading in which those claims were asserted. 921 S.W.2d 711.

Worthy applied to this Court for writ of error, contending that none of her claims are preempted by the FDCA and that she has preserved that complaint for all her claims. Because the preemption issue is a difficult and recurring one, we granted Worthy's application.

II

Before turning to the preemption issue, we must first address Worthy's preservation argument. Worthy failed to include in the clerk's record on appeal her original pleading in which she asserted the causes of action dismissed by the first summary judgment. When she discovered the omission, she moved the court of appeals for leave to supplement the record. The court granted her motion, but Worthy did not file the supplemental record due, according to her, to "miscommunication". When the court issued its opinion

holding that Worthy had failed to preserve her complaint concerning dismissal of the claims in her original pleading, she again moved to supplement the record. This time the court denied her motion, explaining in an opinion on rehearing: "Worthy has made no showing of any unusual circumstances that would justify allowing her to supplement the record at this late date. Indeed, Worthy does not even attempt to explain her failure to include her original petition in the appellate record prior to submission of the case." 921 S.W.2d at 723.

Worthy argues that the court of appeals abused its discretion in denying her leave to supplement the record. Former Rule 55(b) of the Texas Rules of Appellate Procedure required an appellate court to grant a party leave to supplement the record prior to submission unless it would unreasonably delay disposition of the appeal. After submission, however, and after judgment especially, the court has more discretion to deny supplementation. In *Silk v. Terrill*, 898 S.W.2d 764 (Tex. 1995) (per curiam), we held that the court of appeals abused its discretion in denying leave to supplement the record when the omitted item was attached to the party's brief and the party requested supplementation following oral argument and prior to the court's decision. We stated: "Judicial economy is not served when a case, ripe for decision, is decided on a procedural technicality of this nature. In the interests of justice and fair play, cases should be decided on the merits when deficiencies of this nature can be easily corrected." *Id.* at 766. While we adhere to this view, supplementation of the record after a case is decided is a different matter. It certainly does not serve judicial economy for the appellate court to allow a supplementation of the record that would require it to reconsider its decision on the merits when a party has had ample opportunity to correct the

omission prior to decision. The court of appeals decided this case not on a procedural technicality but on a record Worthy failed to supplement even after requesting and being granted leave to do so. The court of appeals did not abuse its discretion in denying leave to supplement the record after its opinion issued.

Worthy also argues that some claims asserted in her original pleading were carried forward in her second amended pleading, so that it is not necessary that her original pleading be in the record. Specifically, she contends that allegations that Zyderm was unsafe and that Collagen breached warranties and withheld information raise claims not only for DTPA violations but for products liability, breach of warranty, misrepresentation, and fraud. Worthy's reading of her second amended petition is not completely unreasonable, but we reject it for other reasons. In her response to Collagen's second motion for summary judgment, Worthy told the district court that her second amended petition asserted only DTPA claims and that Collagen's motion "presents a simply, straightforward legal issue" of whether the FDCA preempts a DTPA cause of action. Furthermore, Worthy told the court of appeals in oral argument that her second amended petition did
not allege any of the causes of action alleged in her original petition. 921 S.W.2d at 722. Having told both lower courts that her second amended petition contained only DTPA claims, Worthy cannot be permitted to argue now for a broader reading of her pleadings.

Finally, Worthy argues that the claims in her original petition are sufficiently referenced in Collagen's first motion for summary judgment to preserve her complaint that they should not have been dismissed. Assuming that grounds for

summary judgment could ever be challenged on appeal without the pertinent pleadings in the record, the court of appeals correctly held that Worthy's claims cannot be sufficiently discerned from Collagen's motion for summary judgment to permit a determination whether they are preempted by the FDCA. That determination requires "a careful comparison" between the claims asserted and the alleged federal requirements. *Medtronic*, __U.S. at__, 116 S. Ct. at 2257-2258. Worthy's claims cannot be adequately ascertained from Collagen's pleadings.

The court of appeals did not err in limiting its consideration to Worthy's DTPA claims. We limit our own consideration as well.

III

A

Our role in determining the extent to which the FDCA preempts state causes of action is a limited one. We are, of course, bound to give effect to the will of Congress. "The 'ultimate touchstone' in every pre-emption case" is the intent and purpose of Congress as discerned primarily from the language of the statutory provision and the context of its enactment, and then through "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Medtronic*, __U.S. at__, 116 S. Ct. at 2250-2251. We are also bound to follow the decisions of the United States Supreme Court, the final authority on federal preemption issues. With these two

masters to guide, the path should perhaps be clearer than it is. The MDA's preemption provision is, in the Supreme Court's words in *Medtronic*, "highly ambiguous". *Medtronic*,___U.S. at___, 116 S. Ct. at 2260 (Breyer, J., concurring). Unfortunately, it may fairly be said that the Court's three opinions in *Medtronic* do not dispel all confusion. As the United States Court of Appeals for the Seventh Circuit recently observed, "although we have an obligation to be absolutely faithful to the holdings of the Supreme Court of the United States, the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to follow." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 910 (7th Cir. 1997). Still, we must attempt to decide what the Supreme Court thinks Congress intended when it enacted the preemption provision in the MDA.

That provision states: "No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). In other words:

(1) A federal requirement made applicable to a device by the MDA preempts

(2) a state law requirement with respect to the device that both

(3) differs from or adds to the federal requirement and

> (4) relates to the device's safety or effectiveness or to any other matter included in the federal requirement.

Clearly, the provision prohibits a state from passing a law that directly conflicts with an FDA regulation or order regarding how a device is to be made. Less clear are what other state laws are "requirements" "with respect to" devices, what pronouncements by a federal authority are "requirements" "applicable to" devices, and what state "requirements" are "different from, or in addition to" federal "requirements".

In *Medtronic*, the Supreme Court held that the FDA's determination that a device is substantially similar to devices marketed before 1976 and thus may be marketed without premarketing approval -- the § 510(k) process -- does not preempt a lawsuit involving state common law negligence and products liability claims that the device was defectively designed, manufactured, and labeled, and that the device violated FDA regulations. Since *Medtronic*, courts have held that a "substantially similar" determination by the FDA under the § 510(k) process does not preempt a suit based on state law for personal injuries caused by a device. *See, e.g.*, *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997); *Reeves v. AcroMed Corp.*, 103 F.3d 442 (5th Cir. 1997); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324 (4th Cir. 1996); *Shea v. Oscor Medical Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996). But *Medtronic* does not directly address what preemptive effect should be given premarketing approval or the comparably rigorous determination that a device qualifies for investigational use. To resolve this issue we must look beyond the holding of *Medtronic* to its rationale.

This task is complicated by the fact that the Supreme Court issued three opinions in *Medtronic*. JUSTICE STEVENS wrote an opinion in parts for a five-member majority but in other parts for a four-member plurality. JUSTICE BREYER wrote an opinion concurring in parts of JUSTICE STEVENS' opinion, and JUSTICE O'CONNOR wrote a concurring and dissenting opinion joined by three other Justices. So many courts have summarized the *Medtronic* opinions that we think it useless to repeat the task. Instead, we assume a familiarity with those opinions themselves and attempt straightway to distill from them precepts pertinent to this case that find support in the views of a majority of the Supreme Court. Some of these precepts have the stature of the Court's holding under the rule that "when the Supreme Court issues a plurality decision, and 'no rationale explaining the result enjoys the assent of five Justices, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds . . . ."'" *Milkiewicz v. Baxter Healthcare Corp.*, 963 F. Supp. 1150, 1155 (M.D. Fla. 1996) (quoting *Marks v. United States*, 430 U.S. 188, 193, 51 L. Ed. 2d 260, 97 S. Ct. 990 (1977), quoting *Gregg v. Georgia*, 428 U.S. 153, 169 n.15, 49 L. Ed. 2d 859, 96 S. Ct. 2909 (1976)). This rule focuses our attention particularly on JUSTICE BREYER's opinion because his grounds for concurring in the judgment are narrower than those stated by the plurality. His views consistent with the judgment must be treated as the Court's holding. But JUSTICE BREYER also joins in parts of JUSTICE O'CONNOR's opinion, and while the Justices on that opinion do not concur fully in the judgment, we believe we should treat as authoritative the matters on which JUSTICE BREYER and JUSTICE O'CONNOR agree. Altogether, then, these precepts are as follows.

B

First: The MDA preempts only state requirements that directly conflict with federal requirements or thwart the purpose of the Act. As JUSTICE BREYER explained, so-called "field" preemption exists when "the scheme of federal regulation is 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it'". *Medtronic*, __U.S. at__, 116 S. Ct. at 2261 (Breyer, J., concurring) (citations omitted). At least a majority of the Supreme Court, and perhaps the entire Court, reads the MDA as not preempting all state regulation. Rather, under the MDA a federal requirement preempts a state requirement if "the state requirement actually conflicts with the federal requirement -- either because compliance with both is impossible, or because the state requirement 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (citations omitted).

Determining whether compliance with both a federal requirement and a state requirement is impossible is a relatively easy matter. But determining whether a state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" is difficult because those purposes and objectives are not adequately defined in either the MDA or the *Medtronic* opinions. A majority of the Supreme Court briefly explained the history and motivation of the MDA:

> As technologies advanced and medicine relied to an increasing degree on a vast array of medical equipment "from bedpans to brainscans," including kidney

> dialysis units, artificial heart valves, and heart pacemakers, policymakers and the public became concerned about the increasingly severe injuries that resulted from the failure of such devices.
>
> In 1970, for example, the Dalkon Shield, an intrauterine contraceptive device, was introduced to the American public and throughout the world. Touted as a safe and effective contraceptive, the Dalkon Shield resulted in a disturbingly high percentage of inadvertent pregnancies, serious infections, and even, in a few cases, death. In the early 1970's, several other devices, including catheters, artificial heart valves, defibrillators, and pacemakers (including pacemakers manufactured by petitioner Medtronic), attracted the attention of consumers, the FDA, and Congress as possible health risks.
>
> In response to the mounting consumer and regulatory concern, Congress enacted the [MDA].

Id. at 2246 (Stevens, J., majority) (citations omitted). The preamble of the MDA states that the statute is "to provide for the safety and effectiveness of medical devices intended for human use". 90 Stat. 539 (1976). Quoting a House Committee report, the FDA has recently observed: "Congress sought 'to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary restrictions.'" 62 Fed. Reg. 65384, 65385 (Dec. 12, 1997) (proposed amendment to 21 CFR § 808.1) (quoting H.R. Rep. No. 853, 94th Cong., 2d Sess. 8 (1976)). A

plurality of the Supreme Court read the last clause as not limiting personal injury lawsuits in any way, but this was clearly not the view of a majority. *Medtronic*, __U.S. at__, 116 S. Ct. at 2253 (Stevens, J., plurality); *id.* at 2261-2262 (Breyer, J., concurring).

While it seems clear both from the statute and the *Medtronic* opinions that Congress did not intend FDA approval of a device to insulate the manufacturer from all liability for injuries resulting from its use, it seems equally clear that Congress did not intend FDA approval as merely a precondition for marketing the device. For one thing, by approving a device the FDA not only allows it to be marketed but prohibits it from being marketed in any way other than as approved. 21 C.F.R. § 814.80 (1997). FDA approval is more of a substantive regulation and not merely a license to sell. For another, FDA review is substantive and regulatory. To obtain premarketing approval, the design, manufacture, distribution, and use of a device are all subject to thorough scrutiny by a panel of experts. The FDA requires adherence to specified standards. Furthermore, if Congress intended only that FDA approval be a prerequisite to marketing of a device and nothing more, there would be little if any need for any preemption provision at all. If FDA approval meant nothing more than that a manufacturer could market a device subject to any and all liability claims that might be made, then JUSTICE STEVENS was correct: preemption of such claims would be "rare indeed". *Medtronic*, __U.S. at__, 116 S. Ct. at 2259 (Stevens, J., plurality). A majority of the Supreme Court expressly rejected this view. *Id.* at 2262 (Breyer, J., concurring); *id.* (O'Connor, J., concurring and dissenting).

In the expansive area between conclusive approval of a

device and mere licensure, however, we are unable to find a clear indication of how Congress intended state and federal regulation of medical devices to be balanced to ensure safety and instill confidence but not stifle innovation. Neither the statute nor the *Medtronic* opinions suggest a general unified theory of medical device regulation to guide preemption analysis. Short of that, there do appear to be two or three basic rules.

C

Second: The more specific a federal requirement under the MDA is, the more likely that that requirement will be deemed preemptive. The FDA's regulation construing the MDA's preemption provision states: "State or local requirements are preempted only when the Food and Drug Administration has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." 21 C.F.R. § 808.1(d) (emphasis added). JUSTICE STEVENS' and JUSTICE BREYER's opinions both endorse this construction of the statute, *Medtronic*, __U.S. at _, 116 S. Ct. at 2257 (Stevens, J.) & 2260-2261 (Breyer, J., concurring), although neither opinion rules out giving a general federal requirement preemptive effect. JUSTICE STEVENS states: "Although we do not believe that this statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted, it is impossible to ignore its overarching concern that preemption occur only where a particular state

requirement threatens to interfere with a specific federal interest." *Id.* at 2257 (Stevens, J., majority).

A determination by the FDA that one device is substantially similar to another is too general to have preemptive effect. On this the Supreme Court was unanimous. In JUSTICE O'CONNOR's words, "the § 510(k) process seeks merely to establish whether a pre-1976 device and a post-1976 device are equivalent, and places no 'requirements' on a device". *Medtronic*, _U.S. at___, 116 S. Ct. at 2264 (O'Connor, J., concurring and dissenting). A majority of the Supreme Court also rejected the argument that the FDA's Good Manufacturing Practice regulations, 21 C.F.R. §§ 820.20-.198 (1997), and labeling requirements, *id.* § 801.109, are specific enough to have preemptive effect. *Medtronic*, _ U.S. at__, 116 S. Ct. at 2256-2257 (Stevens, J., majority). A majority of the Court does not suggest whether premarketing approval might have preemptive effect but does contrast the PMA and § 510(k) processes:

> The "premarket approval," or "PMA" process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.
>
> * * *
>
> The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. As one commentator noted, "the attraction of

> substantial equivalence to manufacturers is clear. [Section] 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."

Medtronic, U.S. at , 116 S. Ct. at 2247 (Stevens, J., majority) (citations omitted). Three times on one page the majority calls the PMA process "rigorous". *Id.*

D

Third: Causes of action for damages based on state law impose requirements within the meaning of the MDA. In JUSTICE O'CONNOR's words, "state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA." *Medtronic*, ___U.S. at___, 116 S. Ct. at 2262 (O'Connor, J., concurring and dissenting). Citing the holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-522, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992) (plurality opinion), *id.* at 548-549 (Scalia, J., concurring and dissenting), JUSTICE O'CONNOR added:

> Whether relating to the labeling of cigarettes or the manufacture of medical devices, state common-law damages actions operate to require manufacturers to comply with common-law duties. As *Cipollone* declared, in answer to the same argument raised here that common-law actions do not impose requirements, "such an analysis is at odds both with the plain words" of the statute and "with the general understanding of common-law damages actions." If § 360k's language is given its ordinary meaning, it clearly pre-empts any

> state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA -- just as it would pre-empt a state statute or regulation that had that effect.

Medtronic, _U.S. at__, 116 S. Ct. at 2262-2263 (O'Connor, J., concurring and dissenting) (citation omitted). JUSTICE BREYER stated, "I basically agree with Justice O'CONNOR's discussion of this point and with her conclusion", *id.* at 2259 (Breyer, J., concurring), and added: "I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action", *id.* at 2260. JUSTICE O'CONNOR acknowledged JUSTICE BREYER's agreement, *id.* at 2263 (O'Connor, J., concurring and dissenting), thus confirming that the view she expressed was that of a majority of the Supreme Court. JUSTICE STEVENS' contrary view that "it will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device'", *id.* at 2259 (citation omitted), was expressly rejected by a majority of the Supreme Court. *Id.* at 2262 (Breyer, J., concurring); *id.* (O'Connor, J., concurring and dissenting).

However, the portions of JUSTICE STEVENS' opinion joined by JUSTICE BREYER include the following passage:

> The general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds

> of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers.

Id. at 2258 (Stevens, J., majority). There is some tension between this view and that expressed by JUSTICE BREYER in his own opinion, as well as with the view expressed by JUSTICE O'CONNOR and with which JUSTICE BREYER expressly agreed. To reconcile these views, we take JUSTICE BREYER's position to be that while a federal requirement would ordinarily not preempt general state common law requirements such as a duty of care or a duty to warn in the abstract, a federal requirement would preempt a particularized application of such duties that imposed a specific "standard of care or behavior" different or in addition to the federal requirement. *Id.* at 2260 (Breyer, J., concurring). We think

this is reflected in the example JUSTICE BREYER chose to illustrate his position:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards "different from, or in addition to" federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes. Where Congress likely did not focus specifically upon the matter, I would not take it to have intended this anomalous result.

Id. at 2259-2260 (citation omitted). Inasmuch as it appears that the dissenting Justices would not disagree with this example, we take it to be the view of a majority of the Supreme Court that a federal requirement concerning a device can preempt a suit in which the claim is that the device should have been made or marketed differently provided, as we have already observed, the federal requirement is sufficiently specific.

E

Fourth: FDA regulations guide construction of the MDA's preemption provision but are not controlling. In expressing her disagreement, JUSTICE O'CONNOR summarized the other opinions as follows:

> To reach its particularized reading of the statute, the Court imports the interpretation put forth by the FDA's regulations. Justice BREYER similarly relies on the FDA regulations to arrive at an understanding of § 360k. 116 S. Ct. at 2260-61. Apparently recognizing that Chevron deference is unwarranted here, the Court does not admit to deferring to these regulations, but merely permits them to "inform" the Court's interpretation. *Ante*, at 2255. It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference, cf. *Smiley v. Citibank* (South Dakota), N.A., 517 U.S. 735, 116 S. Ct. 1730, 1734, 135 L. Ed. 2d 25, but one pertaining to the clear statute at issue here is surely not. "If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664, 113 S. Ct. 1732, 1737, 123 L. Ed. 2d 387 (1993). Where the language of the statute is clear, resort to the agency's interpretation is improper. *See Chevron U.S.A. Inc., v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-843, 104 S. Ct. 2778, 2781-2782, 81 L. Ed. 2d 694 (1984). Title 21 U.S.C.

> § 360k(a)(1) directs the pre-emption of "any [state] requirement" "which is different from, or in addition to, any requirement applicable under [the FDCA] to the device." As explained above, and as Justice BREYER agrees, 116 S. Ct. at 2259-60, the term "requirement" encompasses state common-law causes of action. The Court errs when it employs an agency's narrowing construction of a statute where no such deference is warranted. The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on "any requirement" exists.

Medtronic, __U.S. at__, 116 S. Ct. at 2263 (O'Connor, J., concurring and dissenting) (emphasis in original). As JUSTICE O'CONNOR notes, although JUSTICE STEVENS stated that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect", and that "the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' and, therefore, whether it should be pre-empted", *id.* at 2255 (Stevens, J., majority) (citation omitted), he stopped short of giving the FDA's regulations controlling authority. Rather, he stated: "The ambiguity in the statute -- and the congressional grant of authority to the agency on the matter contained within it -- provide a 'sound basis' for giving substantial weight to the agency's view of the statute." *Id.* at 2256 (citation omitted). In JUSTICE BREYER's words, the FDA should be given "a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect." *Id.* at 2260 (Breyer, J., concurring).

Both opinions accept the FDA regulation's limitation of preemption to "specific" requirements. Whether a majority of the Supreme Court would accept further limitations by the FDA is unclear. Presumably, JUSTICE BREYER would hold that a "2-inch" requirement on a hearing aid wire would preempt a different state requirement, even if the FDA thought it should not. After all, the scope of preemption has been set by Congress, and the agency has no discretion to prescribe either or more or less preemptive effect to its actions. The agency can only provide guidance in assessing the regulatory scheme as a factor in discerning Congressional intent in the statute.

III

With these precepts we now attempt to determine whether the present action is preempted. We look first to the FDA's actions with respect to Zyderm, then to Worthy's claims.

A

1

Since *Medtronic*, several courts have considered whether the PMA process results in requirements specific enough to be given preemptive effect. Most have answered yes. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Easterling v. Cardiac Pacemakers*, Inc., __ F. Supp. __, __ (E.D. La. 1997) ("The FDA's affirmative approval of the device and its subsequent modifications [in the PMA process] constitute device-specific requirements."); *Milkiewicz v. Baxter Healthcare Corp.*, 963 F. Supp. 1150, 1156 (M.D.

Fla. 1996) ("As a result of the PMA process, the FDA regulates the particular device undergoing review by ensuring that it meets specific requirements, then provides approval for those devices 'that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval.' 21 C.F.R. § 814.2(a)."); *Steele v. Collagen Corp.*, 54 Cal. App. 4th 1474, 63 Cal. Rptr. 2d 879, 882 (Cal. Ct. App. 1997) ("Most courts that have dealt with the issue of MDA preemption with respect to Class III devices that have passed through the PMA process, including cases involving Zyderm, have concluded that some or all state common law claims are preempted."); *Armstrong v. Optical Radiation Corp.*, 50 Cal. App. 4th 580, 57 Cal. Rptr. 2d 763, 771 (Cal. Ct. App. 1996) ("In approving [the product] through the PMA process, the FDA imposed federal requirements specific to that product which govern virtually every aspect of its production and sale."); *Kernats v. Smith Indus. Medical Sys. Inc.*, 283 Ill. App. 3d 455, 669 N.E.2d 1300, 1308, 218 Ill. Dec. 774 (Ill. App. Ct.), *app. denied*, 169 Ill. 2d 569, 221 Ill. Dec. 439, 675 N.E.2d 634 (1996), *cert. denied*, __U.S. _, 118 S. Ct. 684, 139 L. Ed. 2d 631 (1998)("We conclude, as have the majority of courts, that the PMA process is a specific federal requirement."); *Mears v. Marshall*, 149 Ore. App. 641, 944 P.2d 984, 993 (Or. Ct. App. 1997) ("Without question, [the PMA process completed by Zyderm] established requirements that governed nearly every aspect of Zyderm's commercial existence."); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, __U.S.__ , 117 S. Ct. 1695, 137 L. Ed. 2d 540 (1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 516 (R.I. 1997), *cert. denied*, _U.S.__ , 118 S. Ct. 374, 139 L. Ed. 2d 291 (1997) ("We conclude that the premarket approval process constitutes a specific federal interest as contemplated in *Medtronic* and that, therefore, the

FDA approval served to impose strict FDA requirements upon the defendant."); *Wutzke v. Schwaegler*, 86 Wash. App. 898, 940 P.2d 1386, 1391 (Wash. Ct. App. 1997) ("The general consensus is that the rigorous process of the PMA results in approval of a device's design that rises to the level of specific federal requirements.") . See also *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir.), *cert. denied*, 516 U.S. 815, 116 S. Ct. 67, 133 L. Ed. 2d 29 (1995); *Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 515 U.S. 1161, 115 S. Ct. 2614, 132 L. Ed. 2d 857 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422-1423 & n.3, 1424 n.8 (5th Cir. 1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 510 U.S. 824, 126 L. Ed. 2d 52, 114 S. Ct. 84 (1993) (all pre-Medtronic cases). As the Seventh Circuit has observed in connection with Zyderm:

> During the PMA process, the federal government, it can truly be said, has "'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.'"

Mitchell, 126 F.3d at 911 (quoting *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997), *cert. denied*,__U.S. __, 118 S. Ct. 166, 139 L. Ed. 2d 110 (1997), in turn quoting *Medtronic*, ___U.S. at___, 116 S. Ct. at 2258 (Stevens, J., majority)).

A relatively small but insistent minority of courts have held that the PMA process does not in itself result in

preemptive federal requirements. *Lakie v. Smith-Kline Beecham*, 965 F. Supp. 49, 54 (D.D.C. 1997) ("The fact that the PMA process requires certain information and mandates certain procedures from manufacturers does not transform the PMA process *itself* into a specific federal requirement which triggers preemption and protects a manufacturer from suit."); *Comeau v. Heller*, 945 F. Supp. 7, 12 (D. Mass. 1996) ("The Supreme Court was well aware of the distinction between a PMA-approved device and a § 510(k)-approved device, yet it failed to limit the *Medtronic* holding to the latter."); *Walker v. Johnson & Johnson Vision Prods.*, Inc., 217 Mich. App. 705, 552 N.W.2d 679, 684 (Mich. Ct. App. 1996) ("While most federal and state courts that have considered similar arguments have concluded that the premarket approval process satisfies the FDA's preemption rule and preempts state common-law claims, we agree with the court in *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458-1459 (9th Cir. 1995), *cert. denied*, _ U.S.___, 116 S. Ct. 2579, 135 L. Ed. 2d 1094 (1996)] that these courts have failed to consider whether Class III medical devices as a group can constitute a 'particular device' within the FDA's understanding of that term."); *Sowell v. Bausch & Lomb, Inc.*, 230 A.D.2d 77, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997) ("While a PMA review is considerably more rigorous and detailed than the premarket notification process at issue in *Medtronic*, it is, in fact, no more 'specific' a requirement."). *See also Kennedy*, 67 F.3d at 1458-1459 (a pre-*Medtronic* case); *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 853 (Mo. 1996), *cert. dism'd*, __U.S._, 117 S. Ct. 2429, 138 L. Ed. 2d 191 (1997); *c.f. Hernandez v. Coopervision, Inc.*, 691 So. 2d 639, 641 (Fla. Dist. Ct. App. 1997). The views of these courts are summarized in *Sowell*:

> The mere fact that a product has received a PMA, a procedure that was instituted with the purpose of benefitting and protecting consumers, is not a reason to forever shield its distributors from State tort actions based on harm caused by the product. Indeed, it is inconceivable that Congress would have provided for such a draconian result without making itself more explicit.

Sowell, 656 N.Y.S.2d at 21. Or as the pre-*Medtronic* opinion in *Kennedy* said: "Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers." *Kennedy*, 67 F.3d at 1460.

The courts that have considered whether the less rigorous, though still specific, IDE -- investigational device exemption -- process results in preemptive requirements are evenly divided. Four have given IDE approval preemptive effect. *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247-1248 (7th Cir. 1997)(negligent manufacturing claims, however, were not preempted); *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997), *cert. denied*, 1988 W.L. 15431, 139 L. Ed. 2d 751, 66 U.S.L.W. 3472 (January 20, 1998)("Unlike the general federal requirements discussed in *Medtronic*, the regulations governing investigational devices are essentially device specific."); *Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839, 843 (D. Minn. 1997) ("Given the intense nature of the IDE approval process, most courts agree that it imposes device-specific federal requirements.") (negligent manufacturing claims, however, were not preempted); *Berish v. Richards Medical Co.*, 937 F. Supp. 181, 185 (N.D.N.Y. 1996) (IDEs are subject to regulations that "'set forth detailed procedures for determining whether

[IDEs] are safe and effective'" and that are "promulgated for application, not generally to all devices, but to IDEs specifically." (citation omitted)). Four have not. *Shea v. Oscor Medical Corp.*, 950 F. Supp. 246 (N.D. Ill. 1996); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), *cert. dism'd*, ___U.S.__ , 117 S. Ct. 2429, 138 L. Ed. 2d 191 (1997); *Baird v. American Medical Optics*, 301 N.J. Super. 7, 693 A.2d 904 (N.J. Super. Ct. App. Div. 1997).

Thus, the post-*Medtronic* decisions are divided over whether FDA premarketing approval alone is a specific federal preemptive requirement, but the majority view is that such approval is preemptive of at least some state requirements.

2

Complicating the matter further, however, the FDA has recently expressed its own disagreement with this view of a majority of the courts. On December 12, 1997, the FDA published for comment a proposed rule on MDA preemption to amend or replace section 808.1 of its existing regulations, 21 C.F.R. § 808.1 (1997), "to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the [FDCA]." 62 Fed. Reg. 65384, 65384, 65388 (Dec. 12, 1997). Noting the conflict in the courts over the preemptive effect of the PMA and IDE processes, the FDA stated:

FDA believes that its general regulatory review and approval processes provide a significant measure of protection against the marketing of dangerous or defective medical devices. FDA does not believe, however, that those processes can guarantee the safety of such devices. Accordingly, compliance with general FDA requirements should not broadly preempt State common law remedies, which provide an important (and frequently the only) mechanism for persons to seek redress for injuries resulting from defective medical devices. FDA notes below several situations in which the agency's regulatory activities will typically not preempt State law remedies.

First, FDA's general clearance and approval processes, such as the clearance for marketing under section 510(k) of the act [21 U.S.C. § 360(k)]; the grant premarket approval under section 515 of the act [21 U.S.C. § 360e]; or the grant of an IDE under section 520(g) of the act [21 U.S.C. § 360j(g)], do not, by themselves, preempt State common law claims. Section 521 of the act [21 U.S.C. § 360k] provides for preemption of a State common law duty only if it imposes a requirement that is different from, or in addition to, a specific substantive requirement pertaining to the particular device that has been imposed by or under the act. FDA's action in clearing a product for marketing or granting an application for a PMA or an IDE signifies that the manufacturer's proposal for marketing or use of the device in question satisfies the relevant statutory and regulatory criteria for the clearance, approval, or exemption. It does not

> signify, however, that Congress or FDA has established a specific Federal requirement (e.g., with respect to the design of the device) that supplants a State common law duty.

Second, FDA's notification of deficiencies in, or proposal of modifications to, an application for a PMA or an IDE does not, as a general matter, create specific Federal requirements that have preemptive effect.

62 Fed. Reg. at 65387. The FDA added, however, that it does not view the proposed rule as a change in its position regarding MDA preemption:

> This proposed rule would make no change in the agency's prior or current construction of the scope of section 521 of the act. Rather, the rule would simply clarify and codify the agency's longstanding interpretation of the scope of section 521 of the act as generally not preempting available legal remedies, including State common law tort claims.

Id.

As we have noted, *Medtronic* requires only that the scope of MDA preemption be informed by FDA regulations, not that courts completely defer to them. Preemption is determined by Congress, not the FDA. *Medtronic* itself accepted from section 808.1 only the limitation that federal and state requirements be "specific". Nevertheless, we are mindful of the view of a majority of the Supreme Court that the FDA is in a unique position to determine the scope of preemption because of its role in the creation of preemptive federal

requirements. Accordingly, we conclude that while a majority of courts since *Medtronic* have viewed PMA and IDE requirements as preemptive, largely irrespective of the details of those requirements, we must look more closely to determine whether such requirements have preemptive effect with respect to a particular device.

3

Prior to *Medtronic*, most courts held that the FDA's approval of Zyderm preempted claims that it was unsafe. *Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *cert. granted & judgment vacated*, 518 U.S. __, 116 S. Ct. 2576, 135 L. Ed. 2d 1091 (1996); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 510 U.S. 824, 126 L. Ed. 2d 54, 114 S. Ct. 86 (1993); *Blanchard v. Collagen Corp.*, 909 F. Supp. 427 (E.D. La. 1995); *Tucker v. Collagen Corp.*, 1994 U.S. Dist. LEXIS 3101, 1994 WL 87367 (N.D. Ill. 1994); *Mears v. Marshall*, 138 Ore. App. 476, 909 P.2d 212 (Or. Ct. App. 1996); 137 Ore. App. 390, 905 P.2d 1154 (Or. Ct. App. 1995), *vacated*, 324 Ore. 130, 921 P.2d 966 (Or. 1996), *on remand*, 149 Ore. App. 641, 944 P.2d 984, 993 (Or. Ct. App. 1997)(post-*Medtronic* opinion). *Contra Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *cert. denied*, _U.S._ , 116 S. Ct. 2579, 135 L. Ed. 2d 1094 (1996); *Fiore v. Collagen Corp.*, 187 Ariz. 400, 930 P.2d 477 (Ariz. Ct. App. 1996).

Since *Medtronic*, most courts have continued to hold that federal requirements on Zyderm preempt most state claims of personal injuries caused by the product. *Mitchell v. Collagen*

Corp., 126 F.3d 902 (7th Cir. 1997); *Steele v. Collagen Corp.*, 54 Cal. App. 4th 1474, 63 Cal. Rptr. 2d 879 (Cal. Ct. App. 1997); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110 (Pa. 1996), *cert. denied*, __U.S.__, 117 S. Ct. 1432, 137 L. Ed. 2d 540 (1997). *Contra Rodriguez-Suris v. Montesinos*, 935 F. Supp. 71, 75 n. 3 (D. Puerto Rico 1996) (court denied summary judgment based upon MDA preemption grounds); *Mears v. Marshall*, 149 Ore. App. 641, 944 P.2d 984 (Or. Ct. App. 1997).

We believe the details of the FDA's premarketing approval of Zyderm -- as opposed to the PMA process in general -- are sufficiently specific to have preemptive effect. Collagen's submissions to the FDA state in detail how the product is manufactured, what its typical immunogenic effect is, what data has resulted from clinical and serological tests, what instructions are given physicians for using the product, what instructions are given patients concerning the product. As we have already noted, Collagen's eight volumes of material were reviewed for over a year by the FDA's panel of experts. The FDA then approved Zyderm, subject to certain detailed conditions. Announcing the order granting approval, the FDA stated that Zyderm "had been shown to be safe and effective". 46 Fed. Reg. 46394 (1981). Ten years later the FDA again reviewed the product and again found it to be safe. As with other products, the FDA prohibited the manufacture or marketing of the product in a manner inconsistent with these conditions. 21 C.F.R. § 814.80 (1997). Given the specificity of Collagen's presentation to the FDA, the specificity of the FDA's conditions in granting approval, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the specific finding by the FDA

that Zyderm was "safe and effective", we conclude that the FDA's requirements concerning Zyderm are entitled to preemptive effect under the MDA as construed and applied in *Medtronic*.

B

We must next consider whether Worthy's claims are preempted. As we have explained, Worthy's claims are solely for violations of the DTPA. Although these are statutory claims, they are similar to common law claims for negligence, breach of warranty, and products liability. In fact, as we noted, Worthy asserted the latter claims earlier in the litigation. *Medtronic* specifically refers to state common law claims rather than claims for violation of a state consumer statute. We see no difference in substance between the two, at least in these circumstances.

Worthy's petition alleges that Collagen represented that Zyderm (and a related product, Zyplast) was safe for her use as a cosmetic device, and that such representations were false, misleading, and deceptive because Worthy developed serious immunological damage and injuries, including autoimmune injuries and damage, and physical deformities and injuries. Worthy alleged that Collagen violated the DTPA by misrepresenting the uses, benefits, standard, quality, and grade of goods; by failing to disclose pertinent information to induce Worthy to use Zyderm; and by breaching the implied warranty that Zyderm was fit for its ordinary purposes. Worthy also alleged that Collagen's conduct was unconscionable.

In essence, Worthy claims that Zyderm was not safe for

her use. She does not contend that Zyderm was manufactured, marketed, or injected in her in any way other than that approved by the FDA. To prevail, therefore, Worthy must prove that Zyderm as approved by the FDA is not safe. This contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA. Collagen cannot both market Zyderm in compliance with FDA requirements and not market Zyderm because it is unsafe. This is not the situation that existed in *Medtronic*. There the plaintiff could obtain a finding that *Medtronic*'s pacemaker was unsafe that did not in any way conflict with an FDA requirement. Here, the FDA requirements specifically and directly contradict what Worthy must prove in order to prevail in her action.

Moreover, we believe that even if the federal requirements for Zyderm could be viewed as not directly conflicting with a judgment favorable to Worthy in her action, claims like hers "'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'" *Medtronic*, ___U.S. at___, 116 S. Ct. at 2261 (Breyer, J., concurring) (citation omitted), as those purposes and objectives relate to this one product. One purpose of Congress is that there be a federal determination whether a device is safe "with respect to the persons for whose use the device is represented or intended, with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2) (subdivision designations omitted). If an action like Worthy's is not preempted, then we are unsure what kind of action would ever be preempted.

As we have previously noted, most courts since *Medtronic* that have considered the issue have concluded as we do that suits challenging the safety of Zyderm are preempted.

* * * * *

For the reasons we have explained, the judgment of the court of appeals is

Affirmed.

Nathan L. Hecht

Justice

OPINION DELIVERED: February 13, 1998

IN THE DISTRICT COURT OF
DALLAS COUNTY, TEXAS

192ND JUDICIAL DISTRICT

CAUSE NO. 92-11942

TEMPIE FORTSON WORTHY,
Plaintiff,

vs.

COLLAGEN CORPORATION AND
JAMES GILMORE, M.D.

Defendants.

ORDER GRANTING SUMMARY JUDGMENT

On this day the Court considered Defendant Collagen Corporation's Motion for Summary Judgment. After reviewing the motion, together with the accompanying memorandum of authorities and supporting affidavit, as well as all other pleadings on file herein, and after reviewing the response of the plaintiff, the Court decided to grant the motion.

It is ORDERED that summary judgment be granted in favor of defendant Collagen Corporation; that plaintiff Tempie Fortson Worthy take nothing by reason of this suit; and that all costs of court be taxed against the plaintiff

SIGNED this 20 day of August, 1993

s/Ted M. Akin
JUDGE PRESIDING

IN THE DISTRICT COURT OF
DALLAS COUNTY, TEXAS

192ND JUDICIAL DISTRICT

CAUSE NO. 92-11942-K

TEMPIE FORTSON WORTHY

V.

COLLAGEN CORPORATION AND
JAMES GILMORE, M.D.

ORDER GRANTING SUPPLEMENTAL MOTION
FOR SUMMARY JUDGMENT

ON THIS DAY the Court considered Defendant Collagen Corporation's Supplemental Motion for Summary Judgment. After reviewing the motion, as well as all other pleadings on file herein, and after reviewing the response of the plaintiff, the Court decided to grant the motion.

It is ORDERED that Defendant Collagen Corporation's Supplemental Motion for Summary Judgment be, and the same is hereby, GRANTED; the Court finding that all claims and causes of action asserted herein by plaintiff Tempie Fortson Worthy, including those asserted in her Second Amended Petition, are preempted by federal law; that plaintiff take nothing by reason of this suit; and that all costs of court be taxed against the plaintiff.

SIGNED THIS 13 DAY OF JUNE, 1994

s/Ted M. Akin
JUDGE PRESIDING

COURT OF APPEALS
FIFTH DISTRICT OF TEXAS AT DALLAS

No. 05-94-01574-CV

On Appeal from the 192nd Judicial District Court
Dallas County, Texas
Trial Cause No. 92-11942-K

TEMPIE FORTSON WORTHY,
Appellant

v.
COLLAGEN CORPORATION,
Appellee

October 31, 1995, Opinion Filed

This summary judgment case presents an unanswered question of law. We decide whether the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act preempt claims brought under the Texas Deceptive Trade Practices Act for damages allegedly resulting from an injection of a cosmetic material known as Zyderm.

In two points of error, Tempie Fortson Worthy complains about the trial court granting summary judgment in favor of Collagen Corporation (Collagen). She contends the trial court erred in concluding that the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA) preempt her claims against Collagen. In considering her points of error, however, we first must address whether Worthy has presented a sufficient record for us to review the trial court's

judgment with respect to every claim she alleged against Collagen during this litigation. We conclude she has not. Worthy has presented a record sufficient for us to review only her claims asserted under the Texas Deceptive Trade Practices Act (DTPA). Therefore, we next address whether the MDA's specific preemption provision, as a matter of law, preempts Worthy's DTPA claims. We conclude it does. We do so after deciding that a regulation promulgated by the Food and Drug Administration (FDA) is inconsistent with congressional intent expressed in the MDA and, therefore, is not controlling. Accordingly, we affirm the trial court's judgment.

FACTUAL AND PROCEDURAL HISTORY

In February 1991, Worthy was injected with a cosmetic device known as Zyderm. Zyderm is a collagen implant material manufactured and distributed by Collagen. Worthy complained that she suffered injuries caused by the injected material. In October 1992, Worthy filed her original petition alleging various causes of action against Collagen. Collagen filed a motion for summary judgment urging that the MDA preempted Worthy's claims. In August 1993, the trial court granted Collagen an interlocutory summary judgment ordering that Worthy take nothing by the claims alleged in her original petition against Collagen.

Following rendition of the judgment, Worthy filed two amended petitions. In her second amended petition, Worthy alleged new causes of action against Collagen solely under the DTPA. These claims were not the subject of the interlocutory summary judgment. Collagen moved for summary judgment with respect to the DTPA claims asserting that the MDA also preempts those claims. In June 1994, the trial court granted

Collagen a second and final summary judgment concluding that federal law preempted all claims asserted by Worthy, including those asserted in her second amended petition. Worthy perfected her appeal to this Court.

Initially, Worthy filed the original transcript of the case in this Court. The only petition contained in the original transcript was Worthy's second amended petition. Worthy later filed a motion for leave to file a supplemental transcript containing her original petition. In her motion, Worthy urged that the original petition was material to this appeal because it set forth the causes of action that were the subject of the trial court's first summary judgment. By signed order, this Court granted Worthy's motion. Nonetheless, a supplemental transcript containing Worthy's original petition was never filed.

DISCUSSION

Record on Appeal

An appellant bears the burden to present an appellate court with a sufficient record showing reversible error. TEX. R. APP. P. 50(d); *Bayoud v. Bayoud*, 797 S.W.2d 304, 313 (Tex. App.--Dallas 1990, *writ denied*); *Nix v. Fraze*, 752 S.W.2d 118, 120 (Tex. App.--Dallas 1988, no writ). Even where an appellant properly requests that all necessary items be included in the appellate record, an appellant still has the duty to be certain that everything material to her appeal is actually received by the appellate court. *Bayoud*, 797 S.W.2d at 313; *Nix*, 752 S.W.2d at 120. By failing to bring forth a sufficient record to show reversible error, an appellant waives any right to complain of the alleged error on appeal. *See*

Sunwest Reliance Acquisitions Group, Inc. v. Provident Nat'l Assurance Co., 875 S.W.2d 385, 388 (Tex. App.--Dallas 1993, no writ).

In this case, the trial court rendered the two summary judgments at different times based upon different pleadings: Worthy's original petition and her second amended petition. The appellate record contains only Worthy's second amended petition. Worthy represented at oral argument that her second amended petition did not allege any of the causes of action raised in her original petition. A review of the second amended petition confirms that it contains claims solely under the DTPA.

As Worthy expressly claimed in her motion to file a supplemental transcript, her original petition is material to this appeal because it sets forth the causes of action that the trial court decided in its first summary judgment. Without Worthy's original petition, we are unable to determine what causes of action the trial court concluded to be preempted in its first summary judgment. We conclude, therefore, that we have an insufficient record to review the trial court's judgment on those claims alleged by Worthy in her original petition. Because Worthy did not provide a sufficient record, she has waived her right to complain of any error involving the issues resolved in the first summary judgment. We affirm, therefore, the trial court's take nothing judgment on the claims alleged by Worthy in her original petition.

We do have within the appellate record Worthy's second amended petition alleging claims under the DTPA. We also have Collagen's motion for summary judgment challenging the DTPA claims in addition to Worthy's response to Collagen's

motion and the trial court's final judgment concluding that the DTPA claims are preempted by federal law. Therefore, we have a sufficient record to review the trial court's final summary judgment to the extent it decided the claims raised in Worthy's second amended petition. Consequently, our review is limited to the DTPA claims raised in Worthy's second amended petition as challenged by Collagen in its second motion for summary judgment, which Collagen designated as a "supplemental" motion.[1]

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[1] The only grounds for and against summary judgment this Court will consider are those that were first presented to the trial court in Collagen's "supplemental" motion for summary judgment and Worthy's response thereto. *See Hall v. Harris County Water Control & Improvement Dist. No. 50*, 683 S.W.2d 863, 867 (Tex. App.--Houston [14th Dist.] 1984, no writ) (the appellate court may address on appeal only those grounds for summary judgment which were expressly presented to the trial court); see also *McConnell v. Southside Indep. Sch. Dist.*, 858 S.W.2d 337, 341 (Tex. 1993). Although Collagen's motion for summary judgment addressing Worthy's second amended petition is labeled a "supplemental" motion, and therefore ostensibly incorporates the grounds for judgment and arguments made in its earlier motion, we conclude that Collagen's "supplemental" motion is a separate and independent motion. *See LLast v. Emmett*, 526 S.W.2d 288, 290 (Tex. Civ. App.--Tyler 1975, no writ) (in determining the nature of an instrument, we look at its substance and not its caption). At the time Collagen filed its "supplemental" motion for summary judgment, its previous motion for summary judgment had been ruled on. Therefore, there was no pending motion to supplement. *See Inman's*

The DTPA Claims

The United States Congress enacted the FDCA, delegating to the FDA the authority to promulgate regulations to enforce the FDCA[2]. In 1976, Congress enacted the MDA, amending the FDCA and granting the FDA comprehensive regulatory authority over certain medical devices. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 360c - 360l (West Supp. 1995). The MDA requires the FDA to classify medical devices intended for human use into one of three classes: class I, II, or III. 21 U.S.C.A. § 360c(b)(1). A class III medical device is subjected to an extensive and rigorous premarket approval process. *See* 21 U.S.C.A. § 360e. The MDA requires premarket approval for class III medical devices because such devices present "a potential unreasonable risk of illness or injury." 21 U.S.C.A. § 360c(a)(1)(C)(ii)(II). Once premarket approval has been given, federal regulations prohibit the device from being "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the [premarket] approval order for the device." 21 C.F.R. § 814.80 (1993). It is undisputed that Zyderm, a material designed to be injected into the human body, is a class III medical device that received premarket approval.

Corp. v. Transamerica Commercial Fin. Corp., 825 S.W.2d 473, 478-79 (Tex. App.--Dallas 1992, no writ).

[2] The FDCA authorizes the creation of regulations for the "efficient enforcement" of the Act, Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 371 (West 1972).

The manner and extent to which a medical device is federally regulated leads to the question of whether a state may also regulate the device or whether the federal statute and regulations preempt, or in effect prevent, such state regulation. Significantly, the MDA contains a specific preemption provision. Section 360k(a) of the MDA states:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a). Although the MDA's preemption provision has been addressed by courts in many other jurisdictions, no Texas appellate court has addressed the effect of the preemption provision on a claim asserted under the DTPA. After reviewing the relevant statutory and regulatory provisions, as well as case law from other jurisdictions, we conclude that section 360k(a) preempts Worthy's DTPA claims.

The scope of the MDA preemption provision is addressed in certain FDA regulations. Among these regulations is section 808.1(b). It states that the "requirements" referenced in section 360k(a) that are subject to preemption include state statutes, ordinances, regulations, and court decisions. 21

C.F.R. § 808.1(b). Section 808.1(d) sets forth examples of various state requirements that, in the opinion of the FDA, are not preempted. *See* 21 C.F.R. § 808.1(d). Among the examples listed is "State or local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electric codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the *requirements are not limited to devices*." 21 C.F.R. § 808.1(d)(1) (emphasis added). Worthy relies on this language in the federal regulations to support her contention that section 360k(a) does not preempt her DTPA claims.

In particular, focusing on the language of section 808.1(d)(1), Worthy argues section 360k(a) does not preempt her claims under the DTPA because the DTPA is a state requirement of "general applicability" that is not "limited to devices." Therefore, urging the FDA's interpretation of the statute, she contends her causes of action should survive. Based upon the following analysis, we disagree.

The FDA's interpretation of the MDA is controlling only if it is not "inconsistent with clearly expressed congressional intent." *Hillsborough County v. Automated Medical Lab., Inc.*, 471 U.S. 707, 714, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985). If the intent is clear, this Court, as well as the FDA, must give effect to the unambiguously expressed intent of *Congress. Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984). We conclude Congress's intent is clear. We also conclude the FDA's interpretation of section 360k(a) as set forth in section 808.1(d)(1) is inconsistent with

that intent and, therefore, is not controlling.

In section 808.1(d)(1), the FDA interprets section 360k(a) to preempt only those state requirements that are limited specifically to medical devices. *See* 21 C.F.R. § 808.1(d)(1). Section 360k(a) states, however, that "any requirement" different from, or in addition to, a federal requirement is preempted when it "*relates to* the safety or effectiveness of the device or to any other matter included in a requirement applicable to a device under this chapter." 21 U.S.C.A. § 360k(a) (emphasis added). The term "relates to" sweeps broadly and encompasses all state requirements that affect medical devices. *Accord Mitchell v. Collagen Corp.*, 870 F. Supp. 885, 892 (N.D. Ind. 1994), *aff'd*,__F.3d__(7th Cir. 1995). The United States Supreme Court has addressed the scope of the term "relates to" in connection with other preemption provisions. In each case the Supreme Court has found state law preempted where it has a connection with or reference to a preemptive plan. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139, 112 L. Ed. 2d 474, 111 S. Ct. 478 (1990) (ERISA); *see also Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 386, 119 L. Ed. 2d 157, 112 S. Ct. 2031 (1992) (Airline Deregulation Act of 1978). Indeed, a law may "relate to" a preemptive plan, and therefore be preempted, "even if the law is not specifically designed to affect such plans, or the effect is only indirect." *Ingersoll-Rand*, 498 U.S. at 139.

In her second amended petition, Worthy alleges causes of action under the DTPA, claiming that Collagen misrepresented Zyderm as safe when, in fact, the product is defective and not fit for the ordinary purpose for which it is to be used. Worthy's claims go to the safety and effectiveness of

Zyderm. Although the DTPA is not specifically directed at medical devices, if Worthy's claims were successful, Collagen would be forced either to meet requirements different from or in addition to the premarket approval requirements or be subjected to DTPA liability. In this case, the DTPA claims clearly "relate to" the safety and effectiveness of the medical device. Guided by United States Supreme Court decisions addressing the scope of the term "relates to," which is the language used in section 360k(a), we conclude the FDA's interpretation of section 360k(a) is not a reasonable interpretation because it is inconsistent with expressed congressional intent. That expressed intent encompasses a broader scope for the MDA than interpreted by the FDA. Accordingly, the regulation is not controlling. Section 360k(a), therefore, preempts Worthy's DTPA claims. To conclude otherwise would negate the purpose of section 360k(a) and allow states to regulate class III medical devices freely through laws of "general applicability."[3]

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[3] There is a split of authority regarding the reasonableness of the FDA's interpretation of section 360k(a) as set forth in section 808.1(d)(1). *See, e.g., King v. Collagen Corp.*, 983 F.2d 1130, 1139 (1st. Cir.), *cert. denied*, 126 L. Ed. 2d 52, 114 S. Ct. 84 (1993) (when statute is clear, agency interpretation must give way); *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 49 (D. Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995) (808.1(d)(1) conflicts with clear intent of congress); *Mitchell v. Collagen Corp.*, 870 F. Supp. 885, 892-93 (N.D. Ind. 1994), *aff'd*, F.3d (7th Cir.) (808.1(d)(1) is contrary to Congress's intent); *see contra Ministry of Health v. Shiley*, 858 F. Supp. 1426, 1435-36 (C.D. Cal. 1994) (citing 808.1(d)(1) as authority); *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633, 635 (S.D. Ohio 1994) (FDA's interpretation in

In her response to Collagen's second motion for summary judgment, Worthy characterizes her DTPA claims as state tort law claims. She contends that this Court should follow the guidance of the Texas Supreme Court in Moore v. Brunswick Bowling & Billiards Corp., 889 S.W.2d 246 (Tex.), cert. denied, 130 L. Ed. 2d 599, 115 S. Ct. 664 (1994), and hold that section 360k(a) does not apply to state tort law. In Moore, the court concluded that the preemption provision of the Federal Boat Safety Act did not preempt state common-law tort claims. In doing so, the court recognized that "jury awards can have an effect akin to regulation" and "the obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 889 S.W.2d at 249. The court held, however, that Congress's intent to preempt state common law was not "clear and manifest" in the Federal Boat Safety Act. This was due, at least in part, to the fact that the Federal Boat Safety Act itself contains a savings clause expressly preserving state common-law claims. 889 S.W.2d at 250.

The *Moore* decision is distinguishable when applied to this case. First, and perhaps most importantly, the MDA, unlike the Federal Boat Safety Act, does not contain a savings

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808.1(d)(1) is reasonable); *Oliver v. Johnson & Johnson, Inc.*, 863 F. Supp. 251, 255 (W.D. Pa. 1994) (claims under Pennsylvania's Uniform Commercial Code not preempted pursuant to 808.1(d)(1)). We consider the cases concluding section 808.1(d)(1) is inconsistent with congressional intent to be more persuasive.

provision.[4] Second, the preemption provision addressed by the court in *Moore* does not contain the "relates to" language found in section 360k(a).[5] As discussed above, this phrase indicates that Congress intended the MDA preemption provision to be broad in scope. Third, the court in *Moore* addressed the preemption of state common law and not a state statutory remedy such as the DTPA. The court noted specifically that the regulatory effect of the common law is not as direct as that of positive enactments. *Id.*

Moreover, numerous courts addressing the issue of the MDA's preemption of state tort liability have concluded that tort liability constitutes a "requirement" as contemplated in section 360k(a). *See, e.g., Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18 (1st Cir. 1994); *Stamps v. Collagen Corp.*, 984

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[4] Although Worthy agrees that section 360h(d) of the MDA constitutes a savings provision, this argument was not presented to the trial court. Therefore, we do not address it here. *Hall*, 683 S.W.2d at 867.

[5] The relevant portions of the Federal Boat Safety Act preemption provision read as follows:

> . . . [A] State or political subdivision of a State, may not establish, continue in effect, or enforce a law or regulation establishing a recreational vessel or associated equipment performance or other safety standard or imposing a requirement for associated equipment . . . that is not identical to a regulation prescribed under section 4302 of this title.

Moore, 889 S.W.2d at 248.

F.2d 1416, 1421 (5th Cir.), *cert. denied*, 126 L. Ed. 2d 54, 114 S. Ct. 86 (1993); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1332-33 (7th Cir.), *cert. denied*, 506 U.S. 917, 121 L. Ed. 2d 246, 113 S. Ct. 327 (1992). In *Stamps*, the Fifth Circuit concluded that Texas tort liability would constitute a requirement different from, or in addition to, the premarket approval requirements applicable to Zyderm. *Stamps*, 984 F.2d at 1421. We agree. This conclusion is supported by the fact that the FDA, whose guidance Worthy previously urged us to follow, has concluded that the scope of preemption under section 360k(a) includes statutes, ordinances, regulations, and court decisions. See 21 C.F.R. § 808.1(b). Nothing in *Moore* dictates a contrary conclusion.

We hold that section 360k(a) preempts Worthy's DTPA claims. We overrule Worthy's first and second points of error. We affirm the trial court's judgment.

JOSEPH B. MORRIS
JUSTICE

CONCURRING OPINION
Before Justices Maloney, Morris, and Devaney
Concurring Opinion by Justice Devaney

Tempie Fortson Worthy appeals the trial court's granting of Collagen Corporation's motion for summary judgment. The trial court ruled that all claims and causes of action asserted by Worthy, including those asserted in her second amended petition, are preempted by federal law. In two points of error, Worthy contends that the trial court erred in granting Collagen

Corporation's motion for summary judgment and in holding that the federal Medical Devices Act preempted her State law claims.

Worthy has brought her appeal with less than a full record of the proceedings in the trial court. An appellant bears the burden to present the appellate court with a sufficient record showing reversible error. TEX. R. APP. P. 50(d); *DeSantis v. Wackenhut*, 793 S.W.2d 670, 689 (Tex. 1990); *Christiansen v. Prezelski*, 782 S.W.2d 842, 843 (Tex. 1990); *Sunwest Reliance Acquisitions Group v. Provident Nat'l Assurance*, 875 S.W.2d 385, 388 (Tex. App.--Dallas 1993, no writ); *Bayoud v. Bayoud*, 797 S.W.2d 304, 313 (Tex. App.--Dallas 1990, *writ denied*). Without a record sufficient to show reversible error, an appellant waives any right to complain of the alleged error on appeal. See *Sunwest*, 875 S.W.2d at 388. Even where an appellant properly requests that all necessary items be included in the record, the appellant still has the duty to be certain that all requested items are actually received by the appellate court. *Bayoud*, 797 S.W.2d at 313. The failure to present a sufficient record requires the appellate court to presume that the omitted portions of the record support the trial court's ruling. *DeSantis*, 793 S.W.2d at 689; *AAA Rapid Concrete Serv. v. Woods*, 818 S.W.2d 178, 180 (Tex. App.--Houston [14th Dist.] 1991, no writ); *Bayoud*, 797 S.W.2d at 313.

The incomplete record becomes apparent in this case because the trial court's final order granted the motion for summary judgment holding that federal law preempted *all* claims asserted by Worthy, including those asserted in her second amended petition, implying that other claims were asserted in prior pleadings not in the record before us. An

examination of the record reveals that Worthy's only pleading in the record before this Court, her second amended petition, alleges only a claim under the Texas Deceptive Trade Practices Act (DTPA).

Therefore, we cannot determine what Worthy refers to when she claims the court erred in denying *all of her tort actions*. If she pled other tort actions in her operative pleading, she would have waived those other actions by filing her second amended petition containing *only* a DTPA complaint. By failing to provide this Court with her original pleadings, upon which the trial court based its judgment, Worthy has waived any error by the trial court on appeal as to other tort claims. Yet, Worthy has asked this Court to decide that the federal Medical Devices Act does not preempt *any* Texas tort law claim or that it preempts *all* Texas tort law claims. We cannot render such a decision because it would constitute an advisory opinion. Neither the Texas Constitution nor the Texas Legislature has vested this Court with the authority to render an advisory opinion. See TEX. CONST. art. II, § 1; *Camarena v. Texas Employment Comm'n*, 754 S.W.2d 149, 151 (Tex. 1988).

Therefore, Worthy's failure to present this Court with a sufficient record to show reversible error waives any right to complain of any alleged error with regard to all tort actions except the one action she has preserved on appeal, to-wit: the DTPA claim. See *Sunwest*, 875 S.W.2d at 388. In the absence of a sufficient record as to those other tort claims, a presumption exists in favor of the trial court's judgment, hence, such judgment will not be disturbed as to those other tort claims. *See Woods*, 818 S.W.2d at 180.

As to Worthy's DTPA claim, I conclude that federal law operates in this instance to establish that Collagen did not misrepresent its product by deception since Collagen's motion for summary judgment is supported by summary judgment evidence that it followed the mandates of the Medical Device Act in the advertising and labeling of the complained-of product. Therefore, I would specifically overrule Worthy's two points of error as to her DTPA claim, and affirm the judgment.

FACTS

In February, 1991, a medical doctor injected Worthy with Collagen Corporation's cosmetic medical device, Zyderm. Zyderm is a processed bovine product marketed for "soft tissue augmentation" for facial defects. Worthy complains that, thereafter, she developed a severe reaction to the injected material, which required reconstructive plastic surgery on her face and immune-suppressant drugs to control the reaction systemically. Zyderm was approved for marketing in 1981 by the FDA pursuant to Pre-Marketing Application procedures of the Medical Device Amendments of 1976.

Congress enacted the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, granting the FDA comprehensive regulatory authority over medical devices. By its terms, the MDA applies solely to medical devices; it does not regulate drugs, cosmetics, foods or other products. Section 360k(a) of the MDA expressly provides as follows:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended

for human use any requirement -

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The MDA requires that the FDA classify each medical device intended for human use into Class I, II, or III. 21 U.S.C. § 360c(b)(1). Only class III devices require premarket approval. 21 U.S.C. § 360e. The stated purpose of premarket approval is to enable the FDA to determine whether a proposed Class III device provides reasonable assurance of safety and effectiveness in its use. There is a rigorous approval process provided for in the federal law. Once a device has been approved for marketing, federal regulations prohibit the device from being "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. The FDA classified Zyderm as a Class III medical device and, consequently, required Collagen Corporation to obtain FDA approval of Zyderm's safety and effectiveness before marketing the product. The summary judgment proof establishes that Collagen's product, Zyderm, has met all the requirements of the applicable federal law.

APPELLANT'S ARGUMENTS UNDER DTPA

Worthy's brief presents arguments that conclude that her

"state tort law claims are not preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug and Cosmetic Act." Thus, her brief, for the main part, fails to specifically address her claims under the DTPA. However, she does provide some guidance in her appeal as to her DTPA claim by stating in one paragraph of her brief that the DTPA is an unfair trade practices law of general applicability and is explicitly not preempted by the federal MDA of 1976. Worthy cites *Bollier v. Medtronic, Inc.*, No. H-92-2439 (S.D. Tex. 1993), as a case that the appellee might cite as one where a local federal judge has preempted DTPA claims under the Medical Devices Act (MDA). Having cited that case, Worthy immediately distinguishes *Bollier* because the plaintiff in that case failed to raise the exclusions contained in 21 C.F.R. 808.1(d)(1). Worthy then draws the conclusion that FDA regulations hold that Worthy's DTPA claims are not preempted. The law that Worthy cites is as follows:

> Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes and the Uniform Commercial Code (warrant of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1).

STATE STATUTES OF GENERAL APPLICABILITY

It appears that federal regulations under the MDA provide that the MDA preempts state statutes which would alter

explicit requirements of the MDA, but do not preempt such statutes of general applicability. The federal plan gleaned from Congressional intent as to medical devices is to carefully regulate the testing, sale, and distribution of medical devices.

Once a product is determined to be subject to the control of the MDA, it is subjected to vigorous tests and labeling as prescribed by the MDA. Any further specific requirements of any state are preempted in order to maintain uniformity in the testing, sale, and distribution of medical devices throughout the nation.

However, while a state may not impose further restrictions on the testing, advertising, and labeling of particular products, which would be by statutes of specific applicability, the regulations do allow states to pass laws of general applicability.

For example, if the federal government were to require wiring for homes to be of a certain composition for the safety of people and their homes throughout the nation, the states presumably would not be permitted to change such specifications. The reasoning would simply be to enable standardization of home wiring for all purposes. However, I see no prohibition against a state passing a law of *general* applicability that would require that all home-wiring had to be run through PVC tubing to protect the wire from accidental damage. Such a state statute would appear to be one of general applicability that would not change the federal mandate on the composition of wiring.

DECEPTIVE TRADE PRACTICES ACT

(DTPA)

Texas adopted the DTPA statute a number of years ago for the protection of consumers generally. That statute is nothing more than a restatement of certain existing common law that allows a consumer to bring an action against a vendor who violates a specific common law tort, such as deceptive or misleading advertising or false labeling that lures consumers by misrepresentation; the DTPA further embodies an existing common law contract remedy for breach of warranty. The DTPA specifies its own special measure of damages for a violation of specific "DTPA" violations. Therefore, I would hold that the Texas DTPA statute is one of general applicability.

However, where a DTPA claim is based upon false advertising and labeling, that specific claim must fail if the complained-of advertising or labeling was prescribed by the federal government under the MDA because the vendor has no control over the advertising and labeling. This would be so because of the vendor's compliance with a federal statute.

In Worthy's second amended petition, she specifically complained that Collagen made representations that were false and misleading, yet the summary judgment evidence establishes that the representations were mandated under the federal law.

Collagen's Motion for Summary Judgment provided summary judgment proof that it manufactured, labeled, and distributed Zyderm in accordance with the mandates of the MDA. Collagen cannot be held responsible for compliance with those mandates. Collagen provided adequate summary

judgment proof to support its compliance with the federal law.

Therefore, because Collagen complied with federal law in its labeling and advertising, it cannot be guilty of misleading Worthy since Collagen had no control over the representations made. My concern is that the order of the court held that the DTPA claim of Worthy was preempted by federal law. As a general statement, I would disagree and hold that the DTPA is a statute of general applicability and is not preempted by the applicable federal law. For example, a DTPA claim of breach of warranty that is based upon a guarantee of performance might very well be the basis of a State action unless the complained of warranty was specifically part of the MDA mandated advertising, which is doubtful since the federal law is designed to protect consumers, not suggest guaranteed results.

My examination of the federal law applicable in this case, when read in context with other sections, makes it clear that State law that would alter the general requirements of a product that comes under the jurisdiction of the MDA will be preempted when such requirements have the effect of establishing a different or additional requirement applicable to a specific device. The following regulation is on point:

> Generally, section [360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, *then the prohibition will be preempted* if the requirement is different from, or in addition to, a Federal requirement established under

the act.

21 C.F.R. § 808.1(d)(6)(ii). (Emphasis added.)

Worthy's lawsuit brought under the DTPA, a statute of general applicability, is not preempted per se, but her specific complaint about the statements made by Collagen as being misrepresentations must fail since Collagen has followed the mandated requirements of the federal law. Since Collagen had no authority to use different language, Worthy's *complaint* is preempted by the federal mandate. The word *preempted* has developed several meanings in law since its first use in English International law, but the word pertains to a first or prior right, or to take precedence. See BLACK'S LAW DICTIONARY 1177 (6th Ed. 1990). In the instant case, the representations made by Collagen met the requirements of federal law and must take precedence over any State test that would find such representations false.

Worthy's claim is that Zyderm's label should have contained specific additional warnings, which would have altered the federal requirements about the product, and, therefore, such additional warnings are preempted by the federally prescribed label. Worthy charges that Zyderm should have been designed, manufactured or marketed in a different manner and that it should not have been marketed at all. Hence, Worthy's complaint seeks to impose additional or different requirements applicable to a device within the meaning of § 360k(a) and 21 C.F.R. § 808.1(d).

Collagen cites a number of cases from across the nation which have specifically held that similar state law causes of action involving Zyderm are preempted by the federal law.

Those cases include: *Mitchell v. Collagen Corporation*, 870 F. Supp. 885 (N.D. Ind. 1994), *aff'd*, No. 94-3946, 1995 WL 576949 (7th Cir.), which involves the Indiana Deceptive Consumer Sales Act, which held that said act was preempted by the MDA; and *Tucker v. Collagen Corporation*, No. 93 C 2375, 1995 WL 87367 (N.D. Ill.). which involves a strict liability law of Illinois, which held that said law was preempted by the MDA. Similar holdings in other states cover this area. *See, e.g., Anguiano v. E.I. DuPont De Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995).

I am not in full accord with those cases insofar as they hold that a statute such as the DTPA statute of Texas is per se preempted by the federal law. I would limit our holding to the facts of this case as I have stated.

Therefore, I would overrule Worthy's two points of error in accordance with this opinion.

I agree that the judgment of the trial court should be affirmed.

JOSEPH A. DEVANY
JUSTICE

COURT OF APPEALS
FIFTH DISTRICT OF TEXAS AT DALLAS

No. 05-94-01574-CV
On Appeal from the 192nd Judicial District Court
Dallas County, Texas
Trial Cause No. 92-11942-K

TEMPIE FORTSON WORTHY,
Appellant

v.

COLLAGEN CORPORATION,
Appellee

February 12, 1996, Motion Denied and Opinion Filed

JUDGES: Before Justices Maloney, Morris, and Devany. Opinion By Justice Morris

OPINION ON MOTION FOR REHEARING

In a timely filed motion for rehearing, Tempie Fortson Worthy asks us to reconsider our opinion issued in this case. We have previously concluded that Worthy failed to provide us with a sufficient record to review any claims other than those set forth in her second amended petition. Worthy now contends, among other things, that the record is sufficient for us to review all her claims or, in the alternative, she should be allowed to supplement the record. In connection with the latter argument, Worthy has filed a motion for leave to file a post-submission supplemental transcript. We deny both

Worthy's motion for rehearing and motion for leave. We write separately to address Worthy's arguments regarding her failure to provide us with a sufficient record.

In our initial opinion, we concluded Worthy failed to provide us with a sufficient record for review because the transcript did not contain her original petition setting forth the specific causes of action upon which the trial court rendered its first summary judgment. The transcript contained only Worthy's second amended petition in which she alleged claims solely under the Texas Deceptive Trade Practices Act (DTPA). The trial court signed a second summary judgment disposing of these claims.

Worthy argues the record is adequate to present the claims raised in her original petition because the claims are "listed" in Collagen Corporation's (Collagen) motion for summary judgment, which is included in the appellate transcript. Worthy additionally points out that the claims are listed in her brief and this listing is not disputed by Collagen. Although there may be instances where we could review claims listed only in a motion for summary judgment, in this case a mere listing of claims is not sufficient to present the claims for review.

The issue presented on appeal was whether the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act preempted Worthy's state law claims. The "list" of the claims purportedly set forth in Worthy's original petition provides us only with the general, descriptive names of the causes of action pleaded. In particular, Collagen's motion for summary judgment describes Worthy's causes of action as negligence, gross negligence, breach of warranty,

strict liability, failure to warn, and fraud in obtaining FDA approval. This list, as contrasted with a pleading made in accordance with well recognized rules of procedure, does not inform us about the specific allegations upon which the claims are based. Without the nature of the allegations supporting the claims before us, any preemption analysis would have to be founded on a "blanket" preemption theory. For example, we would necessarily have to conclude either that all negligence claims are barred or that no negligence claims are barred. Worthy specifically urges us not to apply a blanket preemption analysis, and we agree such an analysis would be inappropriate.

The language of the MDA's preemption provision is broad but not unlimited. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 360k(a) (West Supp. 1995). A state tort claim is preempted only if: (1) the FDA has established regulations specifically applicable to the medical device at issue; (2) the state law claim would impose a requirement different from, or in addition to, the FDA regulations; and (3) the claim relates to the safety and effectiveness of the device or any matter included in a requirement applicable to the device under the MDA. *Accord, Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995). Due to the extensive nature of the premarket approval process, many claims pertaining to Class III medical devices may be preempted. However, there is still the possibility that, based upon the specific facts underlying the claim, one of the three prongs of the test will not be met. To determine how a claim relates to an FDA regulation or requirement, we must review the nature of the allegations specifically supporting the claim asserted. Not to do so would cause us to venture into giving prohibited advisory opinions.

Furthermore, many courts have acknowledged the possibility that certain state-law tort claims will survive preemption. *See, e.g., Duvall v. Bristol-Myers-Squibb, Co.*, 65 F.3d 392, 400 (4th Cir. 1995) (although MDA preempts express warranty claims based on FDA-mandated labeling, packaging, and advertising, it does not preempt express warranties based on manufacturer's voluntary representations), petition for cert. filed, 64 U.S.L.W. 3439 (U.S. Dec. 22, 1995) (No. 95-1010); *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.) (MDA does not preempt claims such as negligent implantation or removal of devices or claims arising out of contaminated devices), *cert. denied* 126 L. Ed. 2d 52, 114 S. Ct. 84 (1993). The distinctive feature of a surviving claim is not its label but its factual basis. For example, an analysis of a claim for negligent implantation of a medical device differs greatly from an analysis of a claim for negligent misrepresentation of a device's effectiveness, although both claims may fall under the label of "negligence." Therefore, although Worthy points to lists of claims contained in the record, these lists do not provide us with a sufficient basis for a complete review in this case.

Worthy next contends the record is adequate to inform us of the claims raised in her original petition because, as she now maintains, the claims are realleged in her second amended petition. Significantly, Worthy's counsel expressly stated during oral argument that the second amended petition did not allege any of the causes of action raised in Worthy's original petition. As we stated in our initial opinion, Worthy's second amended petition appears to allege claims only under the DTPA. We will not now accept Worthy's convenient recharacterization of her pleadings solely to avoid the consequences of her failure to provide us with a sufficient

record.

Alternatively, Worthy requests permission to file a supplemental transcript containing her original petition. It is well settled that a request to file a post-submission supplemental transcript should not be granted, absent some unusual circumstances, after the appellate court has issued its opinion and rendered its judgment. *Irrigation Constr. Co. v. Motheral Contractors, Inc.*, 599 S.W.2d 336, 344 (Tex. Civ. App.--Corpus Christi 1980, no writ); *Archer v. Storm Nursery, Inc.*, 512 S.W.2d 82, 83 (Tex. Civ. App.--San Antonio 1974, no writ). To allow such post-judgment filings would serve only to waste judicial resources, interfere with the orderly administration of appellate review, and impair the principle of finality of judgments.

Worthy has made no showing of any unusual circumstances that would justify allowing her to supplement the record at this late date. Indeed, Worthy does not even attempt to explain her failure to include her original petition in the appellate record prior to submission of the case. It is clear that Worthy was aware of the absence of the pleading because she asked this Court before submission for leave to file a supplemental transcript containing her original petition. In her original motion for leave, Worthy specifically stated that her original petition was material to her appeal. As requested, we granted Worthy leave to file a supplemental transcript containing her original petition, but she never did so. As we stated in our initial opinion, it is the appellant who bears the burden of ensuring a sufficient record on appeal. *See Bayoud v. Bayoud*, 797 S.W.2d 304, 313 (Tex. App.--Dallas 1990, writ denied).

Worthy relies solely on *Silk v. Terrill*, 898 S.W.2d 764 (Tex. 1995), to support her present request to supplement the record. Worthy appears to read *Silk* as broadly requiring that leave be granted upon any request for post-submission supplementation.

At issue in *Silk* was whether the record was insufficient for appellate review because of the absence of an affidavit filed in a summary judgment proceeding. The appeals court concluded the record was insufficient, declined to reach the merits of the case, and denied the appellant's post-submission request to supplement the record. The supreme court held that it was an abuse of discretion not to allow a post-submission supplementation of the appellate record with the missing affidavit. The supreme court's ruling was based on the following: (1) the contents of the omitted affidavit were never at issue because appellee conceded the affidavit negated every element of her claim; (2) the omitted affidavit was not material to a decision on the merits; and (3) the appeals court was provided with a copy of the omitted affidavit before issuing its opinion. *Id.* at 766. The supreme court, therefore, remanded the case to the appeals court for consideration of the merits. *Silk* is inapposite to the facts of this case.

As discussed above, the contents of Worthy's original petition are central to a preemption analysis because it is the petition that sets forth the specific allegations underlying each of her claims. Unlike *Silk*, we have no concessions by the appellee that would inform us of the substance of the missing pleading or make the missing pleading unnecessary to a decision on the merits. Furthermore, Worthy never provided us with a copy of her original petition, even improperly filed, before we issued our opinion and rendered judgment on the

appeal presented at submission. Indeed, Worthy failed to provide us with a copy of her original petition even after obtaining specific leave to do so.

We deny Worthy's motion for rehearing. We also deny her motion to file a post-submission supplemental transcript.

JOSEPH B. MORRIS
JUSTICE

IN THE COURT OF APPEALS
FIFTH DISTRICT OF TEXAS AT DALLAS
NO. 05-94-01574-CV

TEMPIE FORTSON WORTHY,
Appellant

v.

COLLAGEN CORPORATION,
Appellee

ORDER

Before Justices Maloney, Morris, and Devany

The Second Motion for Rehearing filed by appellant TEMPIE FORTSON WORTHY on February 27, 1996 is hereby **DENIED**.

JOSEPH B. MORRIS
JUSTICE
April 16, 1996

Devany, J., concurs

Supreme Court, U.S.
FILED
MAY 29 1998
OFFICE OF THE CLERK

No. 97-1831

IN THE
Supreme Court of the United States
OCTOBER TERM, 1997

TEMPIE FORTSON WORTHY,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of Texas

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MEMORANDUM IN OPPOSITION

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QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts a state statutory claim challenging the safety of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the pre-market approval process under 21 U.S.C. § 360e(c).*

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* Respondent Collagen Corporation has no parent company and no non-wholly owned subsidiaries.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

No. 97-1831

TEMPIE FORTSON WORTHY,
Petitioner,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of Texas

---

MEMORANDUM IN OPPOSITION

STATEMENT OF THE CASE

1. Company history and regulatory background.

In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized petitioner Collagen Corporation ("Collagen") to manufacture and distribute collagen products to be used in various medical treatments. The product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to regulation under the Medical Device Amendments of 1976

("MDA"), 21 U.S.C. §§ 360c-360*l*. With two exceptions not germane to Zyderm, a new Class III medical device may not be introduced to the market until the FDA has determined that it satisfies stringent requirements relating to safety and effectiveness. The proces by which the FDA makes this determination, "known as the 'premarket approval,' or 'PMA' process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." *Medtronic, Inc. v. Lohr,* 116 S.Ct. 2240, 2246-47 (1996). Pursuant to this PMA process, the FDA closely studies the ingredients, components, manufacturing methods, and labeling to be used in conjunction with the device. See 21 U.S.C. § 360e(c), (d); 21 C.F.R. Part 814.

The FDA's approval of a device for marketing pursuant to the PMA process "constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards, and labeling. The FDA's determination is specific to the product." *Mitchell v. Collagen Corp.,* 126 F.3d 902, 913 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998). In addition, "the PMA process imposes requirements that directly affect[] the safety and effectiveness of the product." *Id.* at 911. Once the device has been approved for marketing, the manufacturer is required by the FDA to adhere to all of the standards established during the PMA process concerning how the device is to be "manufactured, packaged, stored, labeled, distributed, or advertised." 21 C.F.R. § 814.80.

Collagen invoked this rigorous PMA process by filing an application with the FDA for premarket approval of Zyderm in May, 1980:

> The initial application consisted of eight volumes containing safety and effectiveness data, in vitro data, animal data, clinical data from tests with more than five thousand patients, a statement of ingredients, a reference to performance standards, labeling, a biblio-

> graphy, significant articles, manufacturing methods, product samples, and patient report forms. . . . In July 1981 the FDA approved Zyderm subject to several conditions. The FDA restricted Zyderm to prescription use and required that it be distributed with FDA-approved labeling and with a patient manual. . . . Finally, the FDA required Collagen to submit a supplemental PMA before making any changes "that may affect the safety or effectiveness" of Zyderm, including changes in use; labeling; manufacturing facilities, methods, or quality control procedures; subcontractors, suppliers, or distributors; sterilization procedures; packaging; and performance or design specifications, components, or ingredients.

Pet. App. 6a-7a. "Announcing the order granting approval, the FDA stated that Zyderm 'had been shown to be safe and effective.' 46 Fed. Reg. 46394 (1981). Ten years later the FDA again reviewed the product and again found it to be safe." Pet. App. 36a.

2. Facts and proceedings in this case.

a. In 1991 petitioner was injected with Zyderm as treatment for facial wrinkles. Pet. App. 45a. Alleging that the treatment had resulted in serious injury, in 1992 petitioner filed suit against both Collagen and her physician in state court, asserting numerous common-law causes of action. Pet. App. 8a-9a. The trial court granted summary judgment for Collagen on the ground that these tort claims were preempted by 21 U.S.C. § 360k(a), the MDA preemption statute. *Id.* at 9a. That statute bars the states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]."

Petitioner then dismissed her physician from the case and filed an amended complaint against Collagen, asserting only a statutory cause of action under the Texas

Deceptive Trade Practices Act ("DTPA"). Pet. App. 9a. "The court again granted summary judgment for Collagen on preemption grounds, and Worthy appealed. The court of appeals held that Worthy's DTPA action was preempted and that she had failed to preserve for appeal any complaint concerning her other claims." *Id.*

b. The Texas Supreme Court affirmed. The court first determined, agreeing with the court of appeals, that petitioner had failed to preserve her common-law causes of action. Pet. App. 9a-12a. Accordingly, the court limited "its consideration to Worthy's DTPA claims." *Id.* at 12a. As a matter of Texas law, petitioner's DTPA claims reduced to the assertion that "Zyderm was not safe for her use. She does not contend that Zyderm was manufactured, marketed, or injected in her in any way other than that approved by the FDA. To prevail, therefore, Worthy must prove that Zyderm as approved by the FDA is not safe." *Id.* at 37a-38a. This cause of action, the court held, is squarely preempted by the MDA. *Id.* at 38a.

After giving full and careful consideration to this Court's decision in *Medtronic,* Pet. App. 12a-27a, and upon review of numerous post-*Medtronic* judicial decisions and regulatory developments, *id.* at 27a-36a, the Court concluded that "the details of the FDA's premarketing approval of Zyderm—as opposed to the PMA process in general—are sufficiently specific to have preemptive effect." *Id.* at 36a. The court explained:

> Given the specificity of Collagen's presentation to the FDA, the specificity of the FDA's conditions in granting approval, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the specific finding by the FDA that Zyderm was "safe and effective," we conclude that the FDA's requirements concerning Zyderm are entitled to preemptive effect under the MDA as construed and applied in *Medtronic.*

Id. at 36a-37a. The court determined that petitioner's state law claim, *i.e.*, that Zyderm is not safe even when produced, sold, and administered in accordance with the FDA's specific requirements, "contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." *Id.* at 38a.

In addition, the court noted that petitioner's claims " 'stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.' " Pet. App. 38a, quoting *Medtronic,* 116 S.Ct. at 2261 (Breyer, J., concurring). Congress intended for the FDA to provide a definitive "federal determination whether a device is safe." *Id.* Because peititoner's cause of action would displace that federal determination with a competing state determination of safety and effectiveness (a determination made not by a panel of experts but, instead, by a jury of laymen), the court observed that "[i]f an action like Worthy's is not preempted, then we are unsure what kind of action would ever be preempted." *Id.*

ARGUMENT

1. The question of MDA preemption presented in this case is the same as that recently presented to the Court in *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied,* 118 S. Ct. 1300 (1998), and *Fiore v. Collagen Corp.*, 930 P.2d 477 (Ariz. Ct. App. 1996), *cert. denied,* 118 S. Ct. 684 (1998), and is also essentially the same as or closely related to those presented in *Kernats v. Smiths Industries Medical Systems, Inc.,* 669 N.E.2d 1300 (Ill. App. 1996), *cert. denied,* 118 S. Ct. 684 (1998), *Martin v. Telectronics Pacing Systems, Inc.,* 105 F.3d 1090 (6th Cir. 1997), *cert. denied,* 118 S. Ct. 850 (1998), and *Eddy v. Polymer Technology Corp.,* 692 A.2d 566 (Pa. 1997), *cert. denied,* 118 S. Ct. 850 (1998). Petitioner offers no better or different reasons for granting the petition here than were offered in those other cases. The Court denied the petitions in those cases and should deny this petition as well.

2. There is no conflict warranting review. The court below, in a carefully reasoned opinion, held that the federal requirements imposed on the manufacturer of a medical device in connection with the FDA's PMA process give rise to federal preemption under 21 U.S.C. § 360k(a). In so holding, the court conscientiously followed this Court's teachings in *Medtronic* and, as petitioner concedes, "[o]ther appellate courts have come to the same conclusion." Pet. 15. Indeed, after *Medtronic* no federal court of appeals or state supreme court has held to the contrary.

The cases upon which petitioner relies in asserting a conflict, *see* Pet. 13-16, either were decided by trial courts or state intermediate appellate courts or, like *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), did not involve medical devices subject to the rigorous requirements imposed by the PMA process. Petitioner has not pointed to a single post-*Medtronic* decision by any federal appellate or state supreme court that is in direct conflict with the decision below.

Indeed, the federal appellate and state supreme courts that actually have considered the question presented here have uniformly concluded that "the PMA process, as opposed to the 'substantially equivalent' process at issue in *Medtronic*, can constitute the sort of specific federal regulation of a product that can have preemptive effect." *Mitchell*, 126 F.3d at 912. *See also Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S.Ct. 1432 (1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I.), *cert. denied*, 118 S.Ct. 374 (1997). The Sixth Circuit in *Martin* and the Ninth Circuit in *Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir.), *cert. denied*, 118 S.Ct. 166 (1997), similarly have found preemption in closely related circumstances. In view of this decisional uniformity, there is neither need nor occasion for the Court to revisit the issues so recently considered in *Medtronic*.

3. As this Court recognized in *Medtronic*, whether section 360k(a) preempts state common law depends importantly on the context. A majority of the Court agreed that state common law duties may constitute requirements subject to preemption under the statute. *See* 116 S.Ct. at 2259-60 (Breyer, J., concurring), 2262-64 (O'Connor, J., concurring in part and dissenting in part). The Court held that the general state common-law requirements invoked by the plaintiffs there were not preempted, "but only after concluding that the federal labeling and manufacturing requirements at issue were not specific to [the medical device in question]." *Papike*, 107 F.3d at 742.

The broad federal requirements at issue in *Medtronic* "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." 116 S.Ct. at 2258. Consequently, the plaintiffs' common-law causes of action in that case did not interfere with the federal regulatory scheme and posed no "threat to federal requirements." *Id.* The Court took care to note, however, that in other contexts "'general' state requirements [may be] pre-empted." *Id.* at 2257. This is precisely such a case. As the Texas Supreme Court noted, petitioner's cause of action runs directly counter to the congressional purposes and objectives of the MDA. Pet. App. 38a.

4. The decision below plainly is not, as petitioner argues, "at odds with *Medtronic*." Pet. 16. This Court in *Medtronic* carefully distinguished between the abbreviated notification process at issue in that case and "the rigorous PMA review" satisfied by Zyderm in this case. 116 S.Ct. at 2247. In *Medtronic* "the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 2254. Here, Zyderm successfully ran that gauntlet and was found to be safe and effective when manufactured and marketed in

accordance with specifications approved by the FDA. 46 Fed. Reg. 46394 (1981).

Although petitioner attempts to obscure the nature of the PMA process and to trivialize the requirements it imposes, that process of determining and assuring safety and effectiveness lies at the very heart of the regulatory program envisioned by Congress when it enacted the MDA. The stated purpose of the MDA is "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic*, 116 S.Ct. at 2245, quoting 90 Stat. 539. The PMA process is the regulatory mechanism by which this purpose is achieved. *Id.* at 2246-47. In turn, a central function of the MDA preemption statute is to insulate that process from state interference: section 360k(a) by its plain terms bars the states from interposing requirements conflicting with or departing from the federal requirements relating to safety and effectiveness imposed pursuant to the PMA process.

5. "During the PMA process, the federal government, it can truly be said, has 'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case . . ., and implemented that conclusion via a specific mandate on [the] manufacturer[].'" *Mitchell*, 136 F.3d at 911. This observation was confirmed, in this case, by "the specificity of the FDA's conditions in granting approval" to Zyderm. Pet. App. 36a.

Petitioner argues, in effect, that such specific federal requirements simply don't count under the MDA preemption statute "because the device's specifications originate with the manufacturer." Pet. 16. That is a nonsequitur. The origin of a federal rule or requirement is irrelevant. A federal agency may, for example, solicit rule proposals from trade groups or individuals. But once the agency adopts a proposal, it becomes the federal standard regardless of origin. That is the case here.

In most (although not all) instances, manufacturing, labeling, and other specifications do indeed originate with the manufacturer. But once the FDA approves those specifications, which it does only after intensive scrutiny, they become specific and binding federal requirements. The PMA approval order typically specifies, and did so in this case, that the manufacturer is required to adhere to the design, components, manufacturing methods, and labeling approved by the FDA in the course of the PMA process. See Pet. App. 6a-7a. Such requirements "are entitled to preemptive effect under the MDA as construed and applied in *Medtronic*." *Id.* at 37a.

6. Petitioner's discussion of her Texas DTPA claims, Pet. 18-20, appears to take issue with the Texas Supreme Court's analysis and characterization of those claims as a matter of state law. The court determined that her claim under the DTPA, in essence, is "that Zyderm was not safe" and that, to prevail, she "must prove that Zyderm as approved by the FDA is not safe." Pet. App. 37a, 38a. That determination, of course, is not subject to review here.

Petitioner's state law claim that Zyderm is not safe "contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." Pet. App. 38a. It therefore is barred by the MDA preemption statute. This is plain common sense. Congress did not intend the FDA's findings of safety and effectiveness to be overridden by state court juries. That is a core principle of MDA preemption. It follows that a firm like Collagen is not subject to state law claims that its product is unsafe when, as here, it has strictly adhered to specific federal requirements in the manufacture and distribution of a medical device that the FDA itself has found to be safe and effective.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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OCTOBER TERM, 1997

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On Petition for a Writ of Certiorari to the Supreme Court of Texas

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The principal reason given by respondent Collagen Corporation for avoiding review is that this Court recently denied review on the same question. *See Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) (No. 97-1018). Petitioner does not, of course, know why the Court denied certiorari in *Mitchell*. But whatever the reason, it does not change the objective facts that favor review here: a deep split of authority in the lower appellate courts on an important issue of federal law—whether state-law damages suits involving medical devices that have received pre-market approval ("PMA") come within this Court's no-preemption ruling in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996).

1. Respondent does not dispute that the question presented is important, and argues only that there is no meaningful conflict of appellate authority. In light of respondent's earlier efforts to obtain review on the same question as the one presented here (*see* Pet. 1), respondent's claim that there is uniformity in the lower courts is simply an attempt to avoid review of a decision favorable to it. As shown in the petition (at 12-16), the conflict among the state and federal appellate courts is substantial and will persist until this Court resolves the preemption issue.

Respondent asserts that the appellate decisions involving devices that have undergone PMA that are in conflict with the Texas Supreme Court's ruling are not from state supreme courts or from federal courts of appeals. Opp. 6. That argument is incorrect. In *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997), the Pennsylvania Supreme Court held that the PMA process preempts some product liability claims with respect to PMA devices, *but not other such claims*. Indeed, respondent filed a cross-petition in No. 96-1451, seeking a complete no-preemption ruling--like the one it obtained in the court below

in this case. *See Collagen Corp. v. Green*, 117 S. Ct. 1695 (1997).

Moreover, respondent is able to assert that the deep decisional conflict is limited to intermediate state appellate courts only by dismissing the post-*Medtronic* rulings in *Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), as involving different circumstances. But the rationales in those cases are flatly at odds with the opinion below. Although *Oja* did not involve a PMA device, it concerned a device for which the Food and Drug Administration ("FDA") had mandated a specific warning. The Tenth Circuit agreed with the defendant that the FDA-mandated warning was specific enough under *Medtronic* to be a preemptive federal "requirement." *Oja*, 111 F.3d at 789. It then held, however, that none of the plaintiff's claims were preempted, regardless of the specificity of the FDA requirement, because the plaintiff's "negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer 'to inform users and purchasers of potentially dangerous items of the risks involved in their use.'" *Id.* (quoting *Medtronic*, 116 S. Ct. at 2258) (internal citations omitted)). Under the Tenth Circuit's reasoning, claims involving a medical device, including a PMA device, are not preempted under *Medtronic*, if damages are sought under general state-law duties applicable to other products in addition to devices. Thus, if petitioner's suit had been filed in the Tenth Circuit, it would survive preemption based on a rationale that cannot be squared with the Texas Supreme Court's ruling below.

The same is true of the Kentucky Supreme Court's decision in *Niehoff*, which concerned a class III medical device marketed under an investigational exemption. Like the Tenth Circuit in *Oja*, *Niehoff* held that none of the plaintiff's claims were preempted, regardless of the potential preemptive effect

of FDA regulations, because "Kentucky's strict liability case law and statutes [on which the plaintiff relied] are laws of general applicability to all products and fall beyond the scope of the federal preemption under [21 U.S.C.] §360k." *Niehoff*, 950 S.W.2d at 822. Thus, *Niehoff* makes clear that tort claims involving medical devices—including PMA devices—are not preempted under *Medtronic* if they are premised on state law of general applicability. *Id.*; *see Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799 (Ky. App. 1998) (interpreting *Niehoff* and *Oja* in that manner).[1]

Respondent does not, because it cannot, challenge the precedential importance of the intermediate appellate rulings cited by petitioner, which hold that a grant of PMA does *not* trigger preemption under 21 U.S.C. 360k(a). Respondent does not deny that the rulings upon which the petition relies are binding in their geographical regions and would permit a suit identical to petitioner's to go forward in those jurisdictions.

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[1] Respondent's attempt to distinguish *Oja* and *Niehoff* is disingenuous at best. Indeed, in the paragraph immediately after respondent dismisses those cases, respondent relies on two federal appellate decisions because they involve, in respondent's words, "closely related circumstances" to those presented by the petition. *See* Opp. 6. But those decisions concern the *identical* issues as those involved in *Oja* and *Niehoff*, and come to diametrically opposed conclusions. *See Papike v. Tambrands, Inc.*, 107 F.3d 737 (9th Cir.) (same issue as before the Tenth Circuit in *Oja*, but taking opposite approach), *cert. denied*, 118 S. Ct. 166 (1997), and *Martin v. Telectronics Pacing System, Inc.*, 105 F.3d 1090 (6th Cir. 1997) (same issue as before the Kentucky Supreme Court in *Niehoff*, but taking opposite approach), *cert. denied*, 118 S. Ct. 850 (1998).

See, e.g., Kernats v. Smith Indus. Medical Sys., Inc., 669 N.E.2d 1300 (Ill. App.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Cal. App. 1996), *review denied*, 1997 Cal. Lexis 833 (Feb. 19, 1997); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997), *review denied*, No. S44987 (Ore. June 2, 1998).[2]

Finally, respondent does not dispute the aspect of post-*Medtronic* confusion that best illustrates the practical consequences of allowing the conflict among appellate decisions to persist. Plaintiffs who file suit for injuries sustained from PMA devices in Illinois and Kentucky will receive different rulings on the critical preemption question depending on whether their cases are litigated in state or federal court. *Compare Kernats*, 669 N.E.2d 1300 (Illinois: no preemption), *with Mitchell*, 126 F.3d 902 (Seventh Circuit: complete preemption), and *Niehoff*, 950 S.W.2d 816 (Kentucky Supreme Court: no preemption), *with Martin*, 105 F.3d 1090 (Sixth Circuit: complete preemption). Similarly, in California, plaintiffs face preemption in one part of the state, but not in another. *Compare Armstrong*, 57 Cal. Rptr. 2d 763 (2nd appellate district: no preemption), *with Steele v. Collagen Corp.*, 63 Cal. Rptr. 879 (Ct. App. 1997) (3rd appellate district: preemption).

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[2] In *Mears*, a case involving a PMA device, the Oregon Supreme Court instructed the Oregon Court of Appeals to reevaluate its earlier pre-*Medtronic* no-preemption holding. *See Mears v. Marshall*, 921 P.2d 966 (Ore. 1996). Relying on *Medtronic*, the Oregon Court of Appeals again found no preemption, and on June 2, 1998, the Oregon Supreme Court denied review. *Mears v. Marshall*, No. S44987 (Ore. June 2, 1998).

2. Respondent suggests that review should be denied because the decision below is correct. Opp. 7-9. The issue at this stage, however, is not whether the preemption issue was handled properly below, but whether the Court should consider that issue at all, and on that score the confusion in the lower courts demands review. But if the merits of the Texas Supreme Court's decision were to enter into the certiorari calculus, petitioner has the better of the argument. *See* Pet. 16-20. Moreover, petitioner takes the same position on the merits as does the FDA, which recently explained to this Court its longstanding position that the Medical Device Amendments ("MDA") do not preempt damages claims involving injuries from devices that have obtained PMA. *See* Brief of the United States as Amicus Curiae in *Smith Indus. Medical Sys., Inc. v. Kernats*, No. 96-1405, at 14-18. That the agency charged by Congress with implementing the MDA believes that the decision below is incorrect underscores the need for review by this Court before petitioner's state-law rights to recovery—and the rights of similarly situated plaintiffs—are forever lost. *See Medtronic*, 116 S. Ct. at 2255-56 (deferring to FDA's preemption views); *id.* at 2261 (Breyer, J., concurring) (same).

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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